Bluetooth Wireless Technology in the Medical Market

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Overview

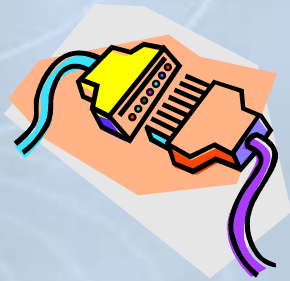
- What needs in medical will Bluetooth address?
- Medical markets for Bluetooth
- Medical device market segments
- Issues
- Demonstration
- Conclusion

What needs will Bluetooth address?

- Eliminate existing cabling
- Provide mobile access to information
- Provide mobile medical data acquisition
- Enable device-device communication
- Enable use of peripherals
- Enable new device architectures

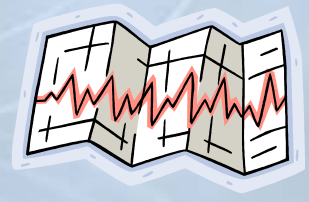
Cable elimination

- Connectors and wires are:
  - Limiting
  - Cumbersome
  - Failure-prone (#1 failure item for most medical devices)
  - Hazardous
- Medical has long needed a cable replacement solution:
  - Cost-effective
  - Low power
  - Reliable
  - International .



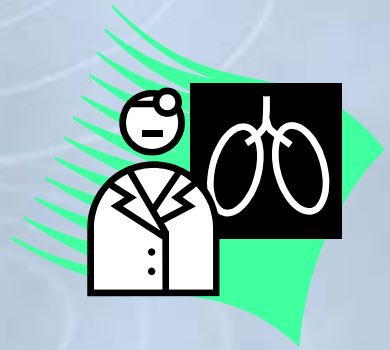
Mobile information access

- ‘Baby boom’ is dramatically lowering care provider to patient ratio requiring more efficient care
- New diagnostic and treatment modalities require
  - Flexibility
  - Leveraged usage of all staff
- Mobile wireless tools enable
  - Greater efficiency
  - Treatment in lower cost facilities or home



Mobile medical data acquisition

- Mobile patients feed data into monitoring systems
- Technology enables mobile healthcare providers
  - Direct access into electronic patient record
  - Reduction in medical errors
  - Increased efficiency



Device-device communication

- Increased efficiency
- Medical error decrease through autonomous configuration and error checking
- Improved resource management
- Increased security through mobile data tags and biometric devices
- Issues with proprietary protocols remain with companies trying to retain market share

Markets for Bluetooth wireless

- Physician personal tools
- Medical devices and diagnostic instrumentation
- Telemedicine .

Physician personal tools

- Physician's Medical Assistant
- Standard database access
  - Rx for dosages, interactions
  - Symptom, disease libraries
- Access to electronic patient records
  - History
  - Test results
  - Decision support tools, expert systems assistance

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Medical and diagnostic devices

- Data acquisition devices for the human body
- Mobile data sources
- Collect data to centralized management system
  - Actually, management systems
  - Devices are managed resources
  - Mobility allows more efficient utilization
- Mobile patients improve outcomes .

An expanded look at devices

Devices in hospital

- Opportunities
  - Connect to mobile devices (eg: PC's, PDA's, tablets)
  - Connect to new Bluetooth devices (eg: printers, tags)
  - Patient Area Network
- Challenges
  - RF environment issues: coexistence, interference
  - Tough users, high expectations, high stakes
  - Limited network size, data rate, overlapping piconets
  - Multiple data management solutions, no standards
  - Security: HIPPA .

Devices in office, clinics

- Opportunities
  - Seamless data connection to office database
  - Connect to WAN for remote referrals
- Challenges
  - Collection of data not part of current practice in US
  - Multiple interfaces
  - Multiple data management solutions, lack of standards .

Devices in emergency medicine

- Opportunities
  - Seamless data connection to WAN, LAN via cellular
  - Eliminate cabling spaghetti and patient safety hazards
  - Remote consultation
- Challenges
  - Environment & abuse (drop, temperature, water, RF)
  - Tough users, high expectations
  - 100% data integrity: fail before false
  - Must be invisible, training is an issue
  - Failure is not an option - no 2nd chances in a ‘code’

Devices in home

- Opportunities
  - Seamless data connections via PSTN or cellular
  - Eliminate cables lowering barriers to use
- Challenges
  - Hostile environment – as tough as emergency?
  - Battery power and management
  - Must be truly user friendly: imagine your Grandmother using it!
  - Reimbursement – ‘who will pay’ issue .

Telemedicine – ‘distance medicine’

- Opportunities
  - Modalities in studies for many years as extensions of the previous devices
  - Enable leveraged use of care resources
  - Wireless as enabling technology
- Issues
  - What to do when wireless ‘goes down’
  - Reimbursement for expensive devices
  - No ‘forcing function’ – to date, but soon??

Bluetooth: regulatory & safety

- Regulatory path:
  - FDA, CE is currently ‘comfortable’ with WMTS (600MHz band, both FM and FHSS)
  - 2.4 Ghz devices have already been cleared
  - Wireless LAN already installed in hospital environments
- There are no known FDA or CE approved Bluetooth medical devices to date (Ortivus?)
- Human safety of 2.4Ghz devices documented in several papers; Bluetooth is very low power .

Medical device issues

- Medical device manufacturers are slow adopters of new technology
  - Product development cycles can be long
  - Large installed base of devices, legacy systems
  - Necessities of environment and cost require custom embedded platforms
  - New modalities must be error-free and seamless
- Industry is highly regulated: FDA, CE
- Industry standards are readily adopted, but proprietary interfaces maintain market share
- Security issues for patient data, US: HIPAA; CE: EPI

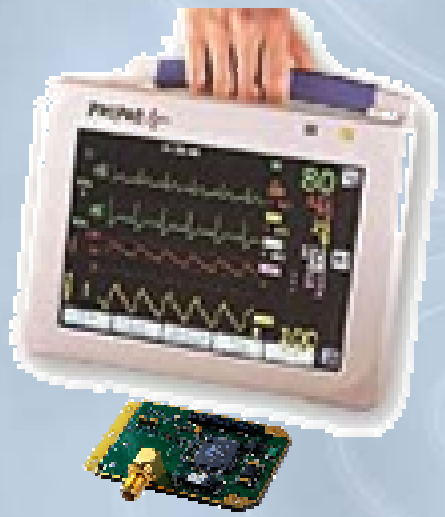
Issues in common

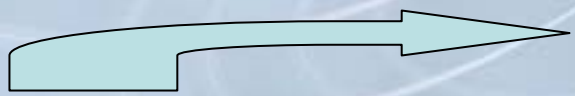
- Reliability, maturity, adoption of technology
  - Need to see devices shipping and in use
  - Interoperability is key!
- Support for custom protocols above transport
- Low power modes necessary for patient worn devices
- Security (Bluetooth is ‘good enough’)
- Ease of use
- International approval
- Knowledge that the technology is ‘here to stay’

Demonstration

For demonstration purposes only: not for sale, or patient use. Propaq® CS, software, and assistance provided by Welch Allyn Protocol.

Bluetooth link using connectBlue Serial Port Adapters enabling legacy software.





Bonus demonstration!

- Nonin Medical patient worn wireless SpO2!!
- Photo to be posted soon…

Conclusion

- Medical devices and medical information management represent opportunities for Bluetooth wireless technology
- The product development and regulatory approval process add extra difficulty to the use of new wireless technology
- As is often the case, the medical market will be slower in adoption than consumer markets