SMART® Modular Technologies
A SOLECTRON COMPANY

Communication Products Division

1GB CompactFlash
SM9FLACF1024M3
Made in USA

Wireless Products
for
Medical Markets

The Value Proposition for Medical Device Manufacturers

Agenda

- Introduction
  - Who is SMART
- Bluetooth
  - The technology and how it applies to Medical
  - Bluetooth value to solutions
- Coexistence
- Available technology and products
- Design & production capabilities
- Next steps

SMART Modular Technologies

- SMART Modular Technologies is a Solectron company, based in Fremont, CA with FY2003 revenues ~ $1.1 billion

- SMART has developed a portfolio of intellectual property consisting of advanced building block level designs and products and partnerships with industry technology leaders.

- SMART is able to leverage Solectron's worldwide manufacturing capabilities, process development, materials management and existing customer relationships.

- SMART is a premier product design and manufacturing outsource solution provider of leading-edge, personal communication systems and products with wireless and wired Personal Area, Local Area and Wide-Area Networks

Quality Commitment

SMART and Solectron have made quality design and manufacturing a priority resulting in the following awards and certifications:

- 1991, 1997 Malcolm Baldridge Quality Award for Manufacturing (Solectron) – first company to win twice
- ISO 9001 (Quality Systems)
- ISO 14001 (Environmental)
- EN46001 (Medical Devices)
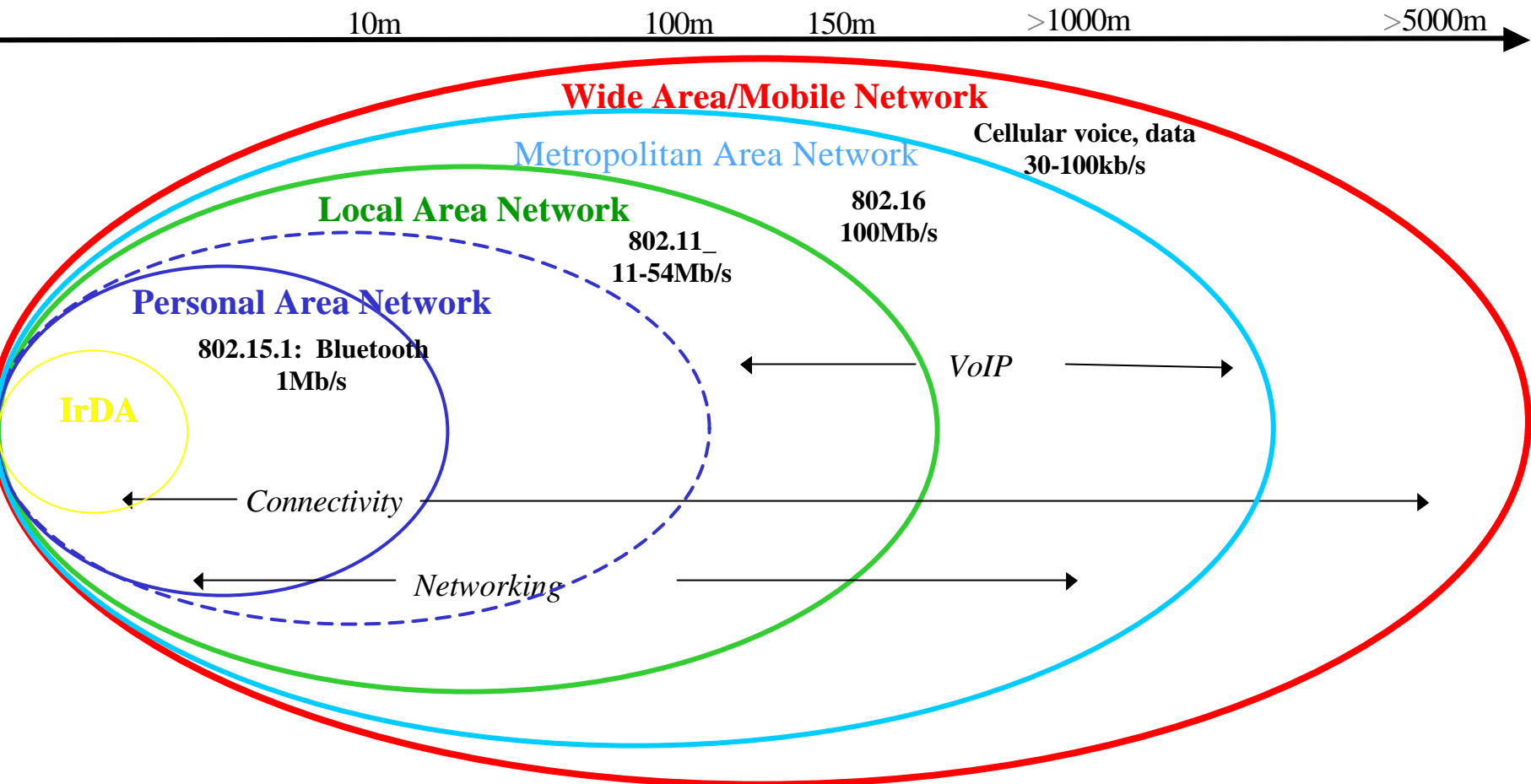- GMP (selected mfg sites)

Manufacturing Strength

- SMART and Solectron have worldwide manufacturing to suite your requirements for: local supply, volume, time to market and price
  - Asia, Americas, Europe

- SMART provides both standard and custom product offerings to fit your needs using reliable and accepted manufacturing and test systems

- SMART and Solectron are one of the largest consumers of components and PCBs in the world. Our purchasing power ensures competitive costs

- SMART and Solectron's manufacturing strength is backed up by numerous certifications and awards

In General: Wireless Technologies & Applications

10m   100m   150m   >1000m   >5000m

Wide Area/Mobile Network

Metropolitan Area Network

Cellular voice, data
30-100kb/s

Local Area Network

**802.16
100Mb/s**

**802.11_
11-54Mb/s**

Personal Area Network

**802.15.1: Bluetooth
1Mb/s**

VoIP

IrDA

Connectivity

Networking

Technology *?* **Products** *?* **Profits**

Specific Technologies Addressed by SMART Modular Technologies, CPD

- Complete span of wireless PAN, LAN, WAN technologies
  - Bluetooth
    - Host (HCI) or adapter resident (complete) stack
    - USB, RS-232 or UART interface
  - Bluetooth & WiFi (802.11b) coexistent
    - Intersil & CSR
    - Mobilian TrueRadio™ with Sim-Op ™
    - Bluetooth 1.2 to come…
  - Cellular GSM/GPRS via PMG

SMART CPD Wireless Products

- Bluetooth Solutions
    - Consumer-Type Products
        - USB Adatper, CF Card, USB Printer Adapter, RS-232 Adapter
    - Modules
        - UART & USB HCI modules (can be loaded with SPP or HID)
        - Serial Class 1 module
- Bluetooth and WiFi (802.11b) Co-existent Solutions
    - MiniPCI
    - Cardbus
- Cellular/GPRS via PMG
    - Mobile Messaging Terminal
    - Personal Mobile Gateway – Client Module (for integration)

Short-Range Wireless Technology Overview

- IrDA (not from SMART)
  - Optical line-of-sight
  - Moderate speed
  - Low power, low cost
- Bluetooth (IEEE 802.15.1)
  - ISM band RF 2.4g
  - Low speed (1Mbps)
  - Low power, low cost
  - Cable replacement, ad-hoc networking (8 device 'piconet)
- WiFi (802.11)
  - ISM band RF (b,g – 2.4G; a - 5.2G)
  - High speed (11, 54Mbps)
  - High power, higher cost
  - LAN infrastructure

Bluetooth Value to Medical Products

- Bluetooth provides the best interface for battery-powered, highly portable and cost constrained devices

- Bluetooth provides access to PAN, LAN, and WAN

- Bluetooth radio minimizes interference potential with and from other devices

Bluetooth Wireless Technology

- Relatively mature wireless communication technology in the ISM band (adopted as IEEE 802.15)

- Designed as low cost, low power cable replacement *plus*

- 10 Meters basic implementation (class 3); 100 meter Class 1

- Relatively low speed (1Mb/sec max)

- 8 device 'piconet'

- Extensive qualification process to assure compatibility and interoperability between devices
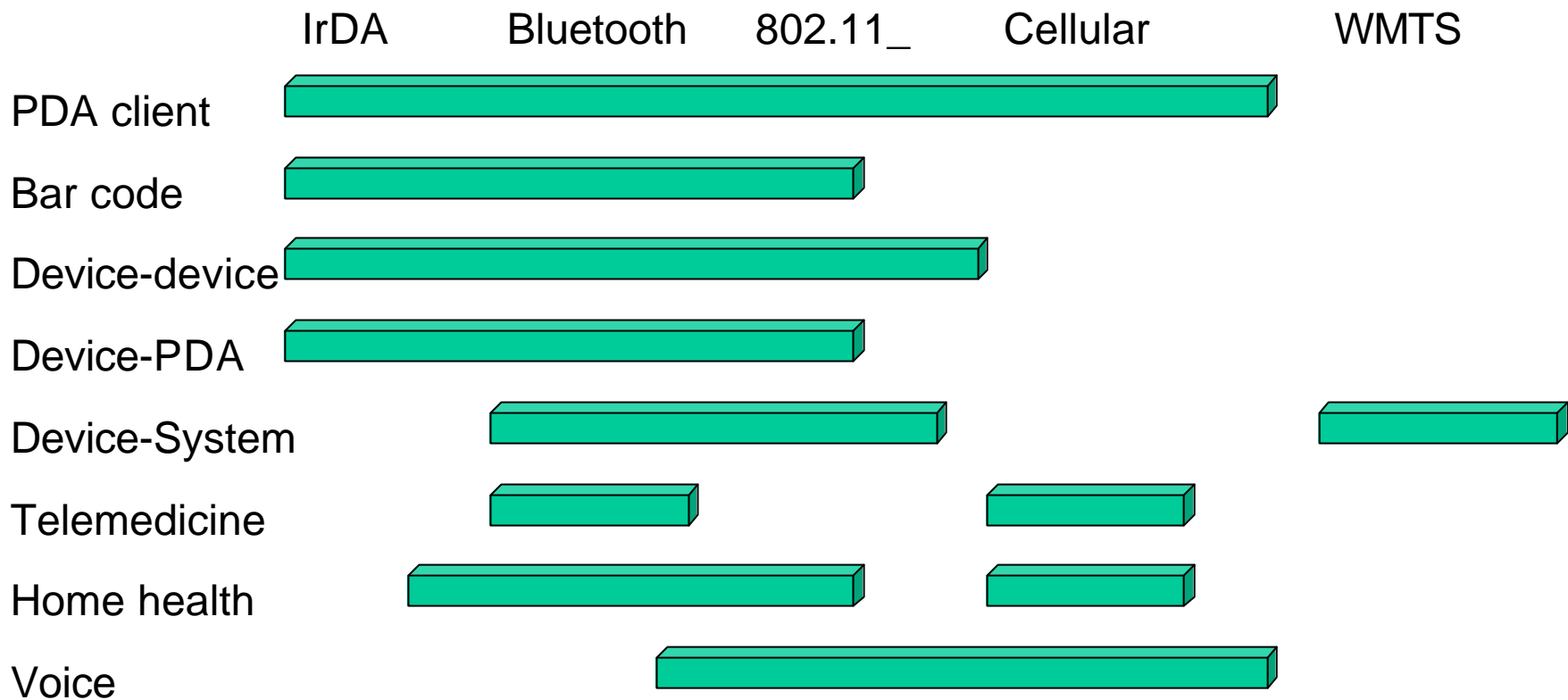
What needs does Bluetooth address?

- 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

SMART
Modular Technologies

Wireless Medical Applications

Chart columns: IrDA, Bluetooth, 802.11_, Cellular, WMTS

Rows:
- PDA client: IrDA → Cellular
- Bar code: IrDA → Bluetooth
- Device-device: IrDA → 802.11_
- Device-PDA: IrDA → Bluetooth
- Device-System: Bluetooth → 802.11_; WMTS
- Telemedicine: Bluetooth; Cellular
- Home health: Bluetooth → 802.11_; Cellular
- Voice: 802.11_ → Cellular

Technology ? **Products** ? **Profits**

The Value of Bluetooth

- Removes cabling
  - Patient hazards
  - Ease of use
- Patient isolation
  - Cost of isolation
  - Immunity from conducted cable noise and motion
  - Cost of connectors + EMI/ESD circuitry
- International wireless standard
  - Same in every country; no tuning or license
- Instant access to wide range of peripherals and communications networks
  - Cellular, LAN, printers, modems, PDAs, computers, …
- Protection from obsolescence with industry standard interface

Bluetooth status

- Specification version 1.1 released February, 2001
  - Solid, Interoperable
  - Formal IEEE 802.15 adoption 04/2002
- Many new profiles released
    - PAN, printer, car, HID
- Revision 1.2 scheduled September 03
  - Adaptive Frequency Hopping co-residence with 802.11 b/g
  - Scatternet definitions
  - Better audio (eSCO)
  - Faster connection
  - QOS – Quality of Service
- Mature hardware and software

Bluetooth Devices Shipping Today

- **Cell phone handsets**
  - Sony Ericsson, Nokia, Motorola, Samsung, Siemens, NEC
- **Audio headsets**
  - Ericsson, Motorola, Jabra, Plantronics, Anycom
- **PDA's**
  - Pocket PC (iPAQ, Jornada, etc), built into iPAQ
  - Palm (Palm, Handspring), built into Tungsten T
- **Laptops**
  - HP, IBM, Sony, etc.
- **Printers**
  - HP, adapters for others
- **USB, PCMCIA/CF Adapters**
- **LAN Access Points**
- **GPS**
- **Keyboard, mouse**

Bluetooth & HIPAA

- Bluetooth meets HIPAA requirements for confidentiality and security between devices
- Bluetooth authenticates & encrypts using 128-bit keys (as yet unbroken)
- Bluetooth security exceeds current 802.11b and provides authentication to use the link

Bluetooth & Reliability

- Excellent immunity (see Bluetooth and the Bovie)
- Error checked and corrected with multiple levels of CRC
- Perhaps the best wireless available

Other issues

- FDA
  - Predicates Approved – no longer needs a 1st approval
    - Ortivus letter to file
    - 510(k) granted June 3 to Stryker (O.R. application)
- EMC
  - Within ISM band, and with other technologies
    - SMART has successfully designed co-existence products
  - FCC approval required; SMART has experience and expertise
  - Much coexistence testing performed with medical devices
- Human safety
  - No issue
- Availability, deployment, staying power
  - Coming on strong!

Bluetooth and Immunity (the Bovie test)

The 'Bovie' (Electro-Surgical unit) is the worst RF emitter in regular hospital usage, emitting literally from DC to light.

In this demonstration, 4 channels of ECG *(continuous waveform; 120W coag. mode)* are being printed, via a Bluetooth print adapter, from 20 ft away while the Bovie is used to cut a chicken breast. *(the 40W florescent light bulb is lighted brightly from the emissions without being connected).*

Bluetooth equipment: GSI/Lumonics recorder prototype, Anycom CF card (Class 3), J&J Ethicon ESU