NEXUS Medical Devices USC
Initial Market Projections
Definition of Medical Devices

- Diagnosis, prevention, monitoring, treatment or alleviation of a disease, an injury or a handicap.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception.
The European Market for Medical devices is estimated at around 40B € and comparable in the USA. Not clear what percentage could benefit from MST.

Following slides try to give an indication as to which markets could benefit from MST.
Establishment of Medical Devices USC

- Formulated over 3 years ago to bring MST experts together with clinical teams and end user manufacturers. This group helped provide the input for the Technology/Product Roadmap published in 2003.
- Quarterly meetings on a range of Clinical topics
Topics covered to date

- Head injury
- Plastic surgery, FES
- Cochlear implants
- Retina implants
- Urology
- Obstetrics
- Heart monitoring
- Wireless comms
- Venture capital funding
The NEXUS Medical Devices Technology/Product roadmap assumes multi-disciplined projects will be formed to develop new products. The sectors considered were Implants, Ambulatory measurement, Point of Care diagnosis and Equipment.
Example: Medical Devices

Implants and Stimulators
- Cochlear implant
- Eye implant
- Shoulder implant
- Heart pacemaker
- Artif. lung/air pump
- Artif. bladder
- Nerve stimulators
- Dropped foot implant

Ambulatory Measurement
- Brain: flow O$_2$
- Chemicals: air intake
- Chemicals: veins
- Pressure/flow: bladder, heart, lung, ...
- Muscle force
- Video
- ...

Point of Care Diagnosis
- Drug delivery
- Bio-analytical tools
- Sample preparation
- µ-optical systems
- Ultrasonic sensors
- ...

Equipment
- Endoscope with
- O$_2$ to brain in blood stream
- Tool to remove bladder/kidney stones
- ...

Cross-application challenges:
Miniaturized RF communication systems, bio-compatible materials/interfaces, packaging of biomaterials, miniaturized power supply, integrated signal processing
Device Roadmap for Implants

1. FES with external systems
   - MST sensors for external trigger
   - MST power syst. for ext. trigger
   - Miniaturized µ-electrodes/ cables
   - Biomaterials for coatings

2. Monitoring implants
   - MST sensors for int. use e.g. gyro, acceler., pressure

3. Active implants e.g. pacemaker
   - New MST µ-pumps/valves
   - Implant development
   - Systems with µ-trigger
   - Reduced size power src.
   - Biomaterials for sensors

4. FES with external unit
   - Wireless data/power coupling
   - New power/data coupling meth.
   - Internal signal processing
   - Power syst. for long term impl.

5. Active implants: electrodes/ sensors intern.
   - MST sensors for int. use e.g. gyro, acceler., pressure
   - µ-electronics for nerve detection
   - New MST internal sensor

6. FES with no external unit
   - Remote controlled implants
   - External communication (e.g. Blue Tooth)
   + links to hospitals/treatment providers

7. Call for Treatment/ alarm trigg.
   - Wireless data/power transm.
   - µ-electronics for nerve detection
   - New MST internal sensor
   - Internal signal processing
   - Power syst. for long term impl.

8. Remote controlled implants
   - Wireless data/power coupling

Time:
- 2002
- 2004
- 2006
- 2008
- 2010
Other Medical Devices Roadmaps

In a more recent national study the sector has been sectioned into:

- Diagnosis
- Preventative Care
- Treatment
- After Care
Diagnosis requires a range of technologies with MST to produce new products. These include:

- Bio and $\mu$-sensors (physical, visual etc)
- $\mu$-packaging, $\mu$-fabrication and interconnects
- Biomaterials
- Power sources
- Motion analysis
- Wireless comms/ GPS
- Clinical trials/ hospitals/ doctors
Diagnostic products that will result include:

- Wearable sensor systems monitoring people at home via hospitals, doctors etc
- Implantable sensor systems monitoring people at home via hospitals, doctors etc
Preventative Care requires a range of technologies with MST to produce new products. These include:

- Bio and $\mu$ sensors and infusion membranes
- $\mu$ fluidic systems, $\mu$ fabrication and interconnects
- Biomaterials
- IT eHealth systems
- Wireless comms/ GPS
- Clinical trials/ hospitals/ doctors
Preventative Care products that will result include:

- Drug delivery systems fitted to people at home and controlled via hospitals, doctors etc
- Elderly/ disabled people monitored in Care homes remotely
Treatment is as detailed in the NEXUS USC roadmap and covers implants, stimulators, equipment (e.g. μrobots).
After Care products will focus on the requirements for monitoring in SMART Care Homes for people returning from hospital, or being kept out of hospital. They include:

- $\mu$ sensors for location movement and motion analysis.
- Health monitoring sensors, e.g. ECG, blood gases, temperature etc.
- Wireless systems, IT eHealth Systems.
Integrated Project (IP) Proposals

- 2 were successful through the Medical Devices USC. One is on implants and ambulatory measurement, ‘Healthy Aims’, the second on Point of Care, SmartHealth.
- Around 25 partners in each one. Both had a Steering group to chose the topics and partners.
- Specific example of the Healthy Aims Project follows.
External force actuators, linked to implants, or other external trigger mechanisms

Signal processing from external trigger mechanism to implant

Note: All implants require power (internal or external), signal processing, communication (internal to external), electrodes, cables
Healthy Aims IP

- 4 year EU Framework 6 Project
  - 15 Workpackages
- €25M total budget
  - EC and Swiss contribution = €16M
- 26 contractors
  - 9 SMEs, 5 LEs, 8 Research, 5 Clinical
  - 10 countries
    - UK, DE, ES, NO, PO, IL, BE, AU, FR, CH
  - Co-ordinator: ETB Ltd.
- Start Date: 1 December 2003
Healthy Aims – Technology development

- Implantable RF communications
- Micro-electrodes
- Miniaturised connection and assembly
- Biocompatible materials
- Power sources
- Sensors and actuation

*Integration of above to specific devices*
Healthy Aims IP – Product Development

- Cochlear (enhancement over existing high cost, low resolution system)
- Retina implant and glaucoma sensor
- FES for upper and lower limbs (enhancement over simple 2 channel ‘Dropped Foot’)
- Artificial intra-urethral sphincter
- Sphincter sensor
- Intracranial pressure sensor for long term implant (>10 years)
Healthy Aims IP – Call for tenders

- End user manufacturer for Intra-cranial pressure sensor for long term implant
- Clinical experts for neuromodulation/neurostimulation applications, including urinary incontinence
- Biomaterials – Potential for medical implants
- Biomaterials test house for medical implant applications
- Mobile comms provider to link into the BAN
- Roadmap for microsystems in Medical Devices
Summary

• Medical Devices is an expanding sector that will benefit from the emergence of a range of new technologies including MST.

• The increase in the ageing population means that the already large market is set to expand considerably over the next 10 years.

• It is clear that MST is only one of the technologies required to produce new intelligent Medical Devices.