Emerging Tag Technology: MEMS/ Nano- RFID

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RFID & Emerging Technologies Market Guide to Healthcare



"Improving the quality of life for those who are touched by healthcare tools"





Medical Device Pedigree

Patient safety and Infection control will be achieved by integrating and tracking the relationship of a medical device's Unique Device Identifier (UDI), to the patient, their procedure, with an automated adverse event and Infection reporting system, generated by the amalgamated results recorded on the patient medical record.

Last Manufacturer

Condition

Medical Device Pedigree". provides possible solutions for the causal effect of cross transfer infections and the spread of disease, from medical devices and instrumentation.

Location=Procedure

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Micro Electro Mechanical Systems

<u>micro scale dimensions (1mm = 1000 microns)</u>

≻electrical and

≻mechanical features

><u>systems</u> (features combined to perform a function)

Two Classes of MEMS- Sensors and Actuators

Sensors – measure and record

Actuators - perform work

MEMS- Sensors

Measure and Record

> Temperature, Humidity, Shock, Vibration, Chemicals, Acoustics, Motion, Light and Voltage

MEMS- Actuators

➢ Magnetic- Force generated by current carrying coil and magnetic field.

Electrostatic - parallel plate or comb drive- electric field upon charged objects.

Piezoelectric generate a voltage in response to applied mechanical stress

Thermal - generates motion by thermal expansion amplification.

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MEMS-ID has developed an unique automated medical device tracking system that addresses <u>critical</u> and <u>immediate</u> unmet needs in the healthcare industry. This technology emulates RFID, enabling affordable tracking of medical instrumentation and supplies, thus providing the solution for Medical Device Pedigree.

MEMS-ID

Benefits over existing methods

- \downarrow errors \Rightarrow improve patient safety
- \downarrow insurance premiums and legal costs
- Improve regulatory compliance and infection control electronically identify use of medical devices, including when associated with an adverse event
- Improve inventory control and supply chain logistics
- Significant cost savings over existing manual/labor intensive methods
- Ability to survive sterilization and gamma irradiation processes



Basics:

- The device measures about 1mm ×1mm packaged in a metallic forming system
- Readout distances dependant on antenna 5mm to 2 feet.
- Resonant frequency is at the 13.56 MHz range
- Thermal endurance -60C to 200C
- Powered by energy transmitted by an external antenna/ reader





Basic Components:

- MEMS-ID chip (core enabling technology)
- Interrogator/reader system
- Proprietary algorithm (key component)
- 19 device, process and material patents by 2008

Source: Mems-ID Inc.

Concept: 256 tuning forks (beams) on a chip = 256 bits



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	Medical Devices	Pharmaceuticals	In Vitro Diagnostics (IVD)
Specific Use Case	Orthopaedic loaner kit instruments and tools	Blood products and vaccines	Re-agents, slides, test tubes and tissue cassettes
Current solution	Data matrix (2-D barcode)	Barcodes Temperature sensors	Barcodes
Value proposition	 ✓ Fully automatic tracking ✓ Survive sterilisation ✓ Ability to write data 	 ✓ Ability to write data ✓ Temperature sensing ✓ Security tag 	 ✓ Ability to write data ✓ Multiple reads in any orientation Source: Mems-ID Inc.

Unique Value Proposition I : MEMS chips have integrated functionality in a single chip

Unique Value Proposition II: MEMS-ID chips are <u>mechanical</u> not an integrated circuit

Unique Value Proposition III : Cost less than traditional RFID chips due to fewer masks, processing steps in the manufacturing process

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Technology Enhancement's Target Markets

 Healthcare – Primary target Surgical instruments Other Medical Devices Pharmaceuticals In-Vitro Diagnostics (IVD) Patient tracking Hospital assets 		 Security Building access control Documents Smart Cards Electronic passports Currency Gaming
Supply Chain/Logistics Postal Packaging Truck & trailer Pallet and container Manufacturing/Warehousing Cold Chain Spare parts Military/defence 	RFID Mems Nano	Retail • Smart checkouts/POS • Smart shelves • Smart trolleys • Retail items
Vehicle Toll collection Parking Key and lock Tyres 		 Books Animal ID Airline baggage Laundry Uniforms



Market Drivers and Applications

Drivers



 Management of instrument lifespan

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Mechanics

- Limited memory capacity
- Antenna Design limitation vs. Distance
- No Processing capability on-chip
- Standards:
 - Interface (Air and Physical)
 - Data Formats
 - Performance (range, data transfer rates)
 - Security
- Technology Dependant
 - Magnetic Resonance Imaging can affect the sensor (MEMS-ID not affected)
 - Ultrasonic Cleaning can damage certain types of MEMS
- Fitting to instruments
 - Changing design of new instruments
 - Retrofitting existing kits –efficiently
- Regulation and Approval of Telemetry Sensor Technology
 - Bio-safety
 - Labeling issue
- Manufacturing Processes
 - Lengthy transfer program from laboratory to commercial foundry

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One US Distribution Center

Source: Mems-ID Inc.

- XXXX employees
- 300,000 instruments/day
- 75% labor savings with RFID Source: HIBCC Auto- ID Technical Committee RFID Case Study Orthopedics RFID Application for "Loaner Set" Logistics January 2006
- Assume 900 employees at \$25k per employee loaded
- Additional Administrative savings

\$22.5M savings per year for one facility

Sales Force and Warehouse Source: FTT 2007

- Typical inventory per distributor close to 10 million dollars
- Loaner kits used in orthopedic surgery; manually counted 10-17 times Mfr \rightarrow SD \rightarrow surgery \rightarrow SD \rightarrow Mfr
- Manufacturer absorbs on average a \$500,000 loss per Branch/ Distributor
- There are on avg. 50 sales reps per branch or \$10,000 of inventory loss per rep a year
- Each Rep has 1.5 hours of paper work a day at an average earning of \$75.00 an hour
- With the Sales Force Ortho Inventory solution one would realize the following savings:
 - \$500,000 in inventory recovery: \$10,000 a rep
 - One half hour of automated paperwork process per rep savings \$9.375 labor
 - **Total System Cost per rep** \$2,250 \$17.175
 - Total annual savings per sales rep

Total annual savings per sales distribution center

\$859,000



Realistic Expectation Adoption Timeline



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- CardioMEMS Inc has designed and received FDA clearance on a new breed of implantable biocompatible microelectromechanical systems (MEMS), that monitor, track, sense and report a patient's condition wirelessly
- These sensors are targeted to reduce mortalities:
 - Abdominal aortic aneurysms
 - Congestive Heart Failure (CHF)
- These Devices address the following technology application improvements:
 - Monitor cardiac patients in real time
 - Designed to provide early detection of heart failure
 - Tells doctors whether they have successfully repaired the walls of the aneurysm sac.
 - Measures the pressure inside the heart
 - Provides doctors with more information, making testing less invasive for patients



Basics:

- The device measures about 30 × 5 mm packaged with fused silica.
- Circular sensors as small as 3.8mm in diameter.
- Readout distances of approximately 8 inches.
- Typical <u>resonant frequencies</u> of sensors are in the 30-40 MHz range



APRIL 2004 I ENDOVASCULAR TODAY



Georgia Tech Photos: Gary Meek Image: Close-up image of a CardioMEMS pressure sensor.

How It Works

The inductors together with their associated distributed capacitance formed the resonant circuit. A change in the embedding pressure would change the relative separation of the coils, and therefore the resonant frequency of the circuit.





Source: Wireless Communicative stent for follow-up of Abdominal Aortic Aneurysm- ENDOCOM project



Georgia Tech Photo: Gary Meek Image: Close-up image of a CardioMEMS pressure sensor.

- 1. The sensor is powered by low power radio-frequency energy transmitted by an external antenna
- 2. The instrumentation block provides a measurement of the absolute pressure.
- 3. The treatment block makes sure that the sensor tasks are operating correctly (acquisition, energy management, emission/reception)
- 4. The communication block contains, in addition to the telecommunication part, and circuit supply management for antenna's output signal.



Market Drivers and Applications

Abdominal Aortic Aneurysms (AAA)

- A condition in which the aorta, the main blood vessel in the abdomen, expands like a balloon; ruptures, or "pops",
- A condition which is usually fatal.
- CT scans <u>only</u> show the size of the aneurysm. Pressure, the most important measurement.
- The first year after receiving a stent graft, FDA recommends four CT scans, reduced to one or two in the following years
- CT each scan costs \$1,500,
- Safety issue due to repeated exposure to radiation and contrast dyes that are toxic to kidneys
- 500,000 patients are diagnosed annually
- 200,000 die from the consequences
- 3rd leading cause of sudden death.
- AAA cost is estimated at \$1 billion by 2008.



Drivers

- Cost savings
- Infection Control
- Lifestyle Flexibility

Instrument lifespan management

- Reduced Risk and Liability
- Remote Diagnostics
- Active illness prevention
- Corporate Medical Programs
- Reduce sudden death mortality
- Reduced adverse events
- Identification and tracking
- High Precision Positioning: Surgery tables, prostheses or medical imaging equipment.

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Technology Challenges

Technology dependant

- Magnetic Resonance Imaging can affect the EndoSure[™] sensor
- Ultrasonic Cleaning can damage certain types of MEMS
- Electrostatic Discharge
- Shock Impact

Regardless of the communication interface, <u>implanted devices must meet</u> <u>parameters for biocompatibility, deliverability</u> - to shield the body from the electronics.

Other Biomedical Tracking/ Sensing Devices

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	ISSYS	 Using <u>magnetic telemetry</u>, the reader transmits power to the implanted te pressure monitoring system and is wirelessly transmitted back to the reat Manufacturing infrastructure is ISO-13485 and FDA GMP compliant. <u>http://v</u> 	elemetric MEMS ader. www.mems-issys.com/	
	 Remon Medical Technologies, Ltd. 	 The size of a grain of rice this <u>acoustic (ultrasound) MEMS</u> contains an exchanger which both energizes and communicates with device. The system can either serve as a sensor, measuring pressure, flow, temp gamma irradiation dosage, or as an activator for localized drug therapie tissue stimulation. <u>http://www.remonmedical.com</u> 	nergy perature, and s and nerve or	
	 Microchip "SoC" 	 Semiconductors are designed for specific medical applications Implanted Devices (cardiac rhythm management, neural stimulation, drug delivery) Portable Devices (diagnostic imaging, oxygen therapy, patient monitoring) Home-Use Devices (vital-sign monitoring, disease management, rehabilitation, compliance monitoring, medical information terminals) http://www.mchips.com/ 		
	 Verichip 	 Metric-Glucose Delivery: Chip is an implanted glucose- sensing, designed Digital Angel patent includes the chip, which is injectable by syringe The implanted chip transmits the information to a scanner The chips are passive, so no battery is required http://www.verichipcorp.com/ 	d for diabetics	
	VTI	 Manufacturer and supplier of sensors for medical research, treatment equinstruments Leading sensor supplier for activity monitoring in cardiac rhythm manage applications. www.vti.fi/en/ 	uipment and Jement (CRM)	
	Kodak	 System to monitor the ingestion of medicines Patent for a digestible radio frequency identification tag, which would mingestion of medicine http://www.rfidjournal.com/article/articleview/3100/1/1/ 	onitor the	
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Nano-Market Applications

Defense	Medical	Electronics	Communication	Automotive
Munitions Guidance Blood Pressure Sensor		Disk drive heads	Optical or Photonic Switches and cross-connects in Broadband networks	Embarked Navigation sensors
Surveillance	Muscle stimulators & drug delivery systems	Inkjet Printer heads RFID Polymers	RF Relays, Switches, and Filters	Air conditioning compressor sensor
Arming Systems	Implanted Pressure sensors	Projection Screen Televisions	Projection displays in portable communications devices and instrumentation	Brake force sensors & Suspension control accelerometers
Embedded Sensors	Prosthetics	Earthquake Sensors	Voltage controlled oscillators (VCOs)	Fuel level and vapor pressure sensors
Data Storage	Miniature Analytical instruments	Avionics Pressure sensors	Splitters and couplers	Airbag sensors
Aircraft Control	Pacemakers	Mass Data Storage Systems	Tunable lasers Source: http://www	"Intelligent" Tires

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Over the next 4 years will MEMS will evolve as a technology architecture becoming an integral part of medical diagnostic and clinical treatment technology.

Value driven by gaining increased patient safety, process efficiencies, reduced cost and providing lifestyle flexibility through new life extending technologies



Provides the framework and proof as the foundation to measure financial and non-financial value creation through the evolution of the market opportunities by the use of new technology

We have past the threshold of theory and process design. Currently we are in the operational implementation phase where technology enhancements will exponentially maximize the utility of every object and event "We make technology easy to live with"

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Thank You



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