



"A Roadmap to Medical Device and Instrumentation Pedigree"
 Intended as an Executive Overview Report

Write to brad@fasttrackrfid.com for response to any questions

Brad Sokol, CEO
Fast Track Technologies, Ltd.

Technical Contributor:
 Bill Newcum: AST Consulting

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Fast Track Technology Ltd, has reviewed four global interoperability models and the Tennessee E-health model, the major oversight in each model is the models inability to incorporate a medical instrument and supply nomenclature into the final product. Each model mentions to need to establish a unified naming system, however due to political and the potential revenue in establishing this relational database, the three main competing databases have been unable to resolve this impasse. There are eight+ secondary and tertiary databases

There is a need to develop a basic globally accepted data format for medical tools that can be linked to a relational database definitions and taxonomy, cross referenced to a Meta-Thesaurus of medical procedures i.e SNOMED.

This data structure needs to be incorporated and mapped into a complex matrix of dynamic hierarchy of unified terms, definitions and procedures of which are to be cross -referenced in a decision tree structure based on relationships, rules and constraints.

Failure to include this basic data structure in a unified medical nomenclature will make the above changes and comparative relationships yield an unstable interoperability healthcare model, costing the healthcare system and medical tool manufactures billions of dollars and expose the public to unnecessary and preventable risks,

The eventual agreement on a universal medical device nomenclature system will be driven by the public's need for accountability and reporting on the progress in addressing the infection control issue.

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Agenda

1. **Medical Device Pedigree -Background- Definition**
2. **Where we are today**
3. **What is the Nomenclature Sequence Code? Registry Service Pointer**
4. **What is the Nomenclature Sequence Server? Registry Service Locator**
5. **What does the new model look like?**
6. **How does the model work?**
 1. **Communication from Centrally Shared De-Referenced Anonymity Database**
 2. **Sub-Network Communication with Decentralized Repositories**
 3. **Remanufacturing, Recalls, Rentals and Loaners**
 4. **Closed loop pedigree model**
7. **Adverse Reporting Infection Control and Medical Device Pedigree**
8. **What will it cost?**

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The public must be made aware of the associated relationship of infection control to a unified medical device nomenclature system. The primary vehicle for infection analysis will be an existing or future interoperable medical error reporting system. This system will provide the channel necessary to trace back (Pedigree) the source of infection (directly or indirectly) to the specific medical tool(s) used in a healthcare infection event.

Failure to incorporate these comparative relationships (Medical Device- Universal Nomenclature- error reporting-patient record/ procedure- EHR) will yield an unstable interoperability healthcare model and will limit our ability to identify, analyze and eventually reduce medical errors and mortalities.

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Objectives of Medical Device Pedigree

Healthcare Advantage:

- **Improved Patient Safety**
 - Prevention of **infectious diseases**
 - **Reduce Mortalities**
 - **Ensure sterilization**
 - **Ensure SUD**
 - **Match surgical equipment and devices to patient schedule/ procedure/ infection cause**
 - **Reduce length of hospital stay increases revenue.**
- **Improved Hospital Efficiency**
 - **Matching patient data records to diagnosis and treatment:**
 - **Timely regulatory preventative maintenance and enforcement of equipment warranties**
 - **Compliance to JCAHO**
 - 2004 National Patient Safety Goals
 - Universal Protocol 5 Rights I-I-05
 - New Pathways 7-I-05
 - Tracer Methodology I-I-06
 - **Inventory management- Error Free Track and Trace and at the instrument level (Set ID, # sterilization)**
 - **Increase Administrative efficiency and billing accuracy**
 - **Reduced Liability and insurance premiums**

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Existing Medical Device Protocols:

IEEE 1073.3.2. Physical Layer ...

- **RS-232** - widely used by medical devices
- low-cost, readily available
- IEC 60601.1 **DC power delivery** - can power devices and adapters
- three power options
- **unpowered DCC/BCC detection**
- ease-of-use; fault detection
- **10BASE-T Ethernet** - high-speed devices [*10BASE-T reserved for future*]
- **RJ-45 connector, CAT-5 cable** - easy-to-use, low-cost connector
- *mandatory* at bedside (BCC)

IEEE 1073.3.2. Transport Protocols ...

- **IrDA protocols**
- IrLAP, IrLMP, and TinyTP**
- widely used standard
- unique device identification
- can support *multiple* upper-layer protocols (MDDL, SNTP, ...)

Multiple upper layer protocols (IrDA Service Access Points)...

- **Medical Device Data Language (MDDL)**
- **Simple Network Time Protocol (SNTP)**
- **Other upper layer protocols (ASTM E-1394)**

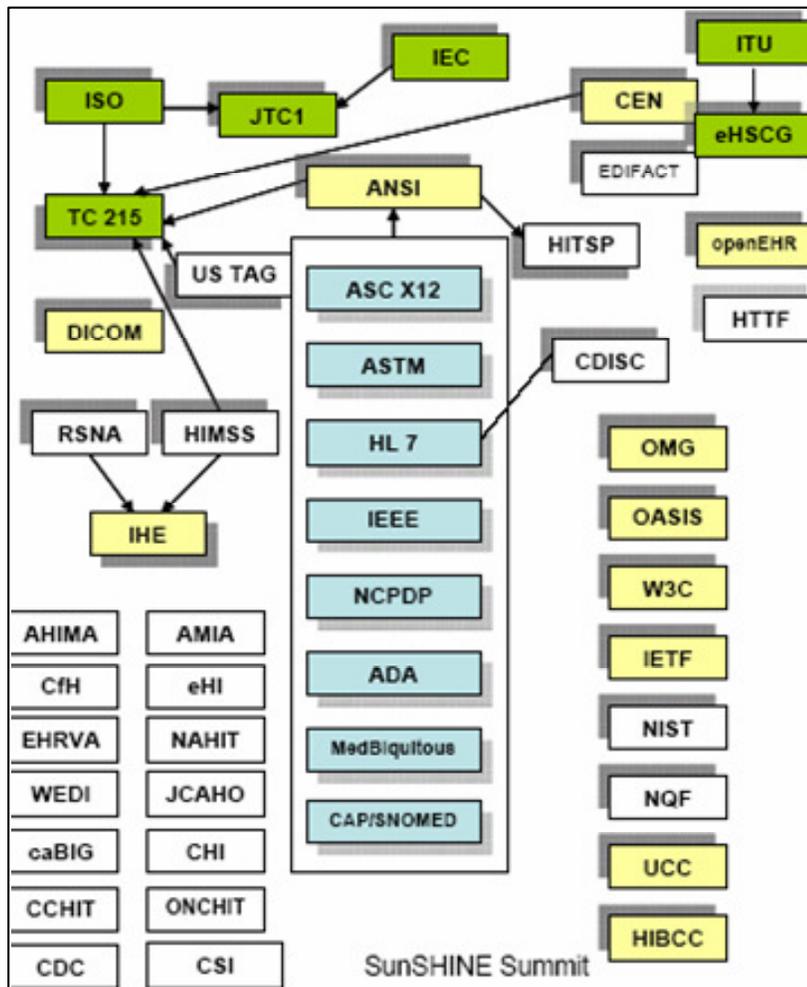
Connectivity Industry Consortium, MEDICA, Düsseldorf, 25 Nov. 2004
NCCLS-POCT1-A: Approval in ISO, CEN, DIN
Using IEE and HL7 components
LabEquipment

Objectives of Medical Device Pedigree

Business Advantage:

- **Increase productivity, increase efficiency** of supply management
- **Lower asset management** and infrastructure costs
- **Increase systems/equipment operational availability**- Revenue
- **Increase in-transit visibility**
- **Lot-level inventory management**
- **Achieve clean audits**
- **Controls to support regional markets and pricing**
- **Adverse Events warnings/notification**
- **Support recalls**
- **Reduce Counterfeit Instruments:**
 - \$2.7 Million seized 6-8-06 (200K from China) <http://www.fda.gov/bbs/topics/NEWS/2006/NEW0387.html>
- **Reduce Liability** and insurance premiums
- **Increase business intelligence**

Healthcare Interoperability Relationships



Source: Hammond 2006

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External Scope

Supply Chain Administrative Inefficiencies

- Every single day the health care supply chain **wastes 24-30%** of supply administration **time on data cleaning and corrections**, costing the health care industry billions of dollars. Resulting in a **\$2 to \$5 billion lost** annually
- Hospitals, GPOS and suppliers spend in excess of **\$5 million dollars** annually to **synchronize product information** —often against non-authoritative sources.
- **Hospital item masters** are constantly being updated. **30%** of buyer systems are **inaccurate**.
- Buyers are sourcing products from old information.
- **60%** of all invoices generated have errors; each invoice error costs **\$40-\$400** to reconcile.
- **Erroneous data increases supply costs 3%-5%**. Each erroneous transaction costs **\$60-\$80** to correct.

Data Synchronization: What is Bad Data Costing Your Company? Sterling Commerce White Paper, 2003 by John Dackor and Coalition of Healthcare eStandards

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Benefits:

JCAHO has two applicable standards, requiring written management plans. Hospitals must have a system for acting on and monitoring recalls, and to track, maintain and test medical equipment. Implementation of a unique device identification system would help hospitals meet their obligations under these standards. JCAHO is concerned that smaller hospitals may not be able to meet their standards.

Decontamination Protocols: "There are no specific FDA rules/regulations that address this issue presently nor any acceptable decontamination protocols." http://www.cmf.org/aboutus/aboutus_show.htm?doc_id=264016 April 2005

Implementation of Electronic Healthcare **Each \$1000 invested in infection control will return \$3000 in net direct cost savings:** **Edward O'Rourke, M.D Harvard University - [Harvard Medical School](#) - Hospital Epidemiology-** "What is it and what is it good for?"

Healthcare Interoperability

Healthcare supply chain issues

Hospital materials management controls

Increase productivity: Late surgical starts and delays during surgery, either due to missing or inoperative instrumentation. <http://www.infectioncontrolday.com/articles/631feat2.html> ,

Reduction of loss instruments: 20 to 30 percent reduction in instrument repair and replacement costs in the next two years: **2005 Computerworld Honors Case Study: Surgical Instrument Management Reduces Surgery Delays and Drives Staff Productivity.** March 2004 at AORN (Association of periOperative Registered Nurses) Congress, Lawson commissioned KRC Research to conduct a survey of OR decision makers to determine the needs of the marketplace.

Inventory Shelf Life accountability

Accurate reporting of Adverse Events involving Medical Devices, Instrumentation and supplies

Reduced liability exposure: <http://www.crn.com.au/story.aspx?CIID=25706&CIPseq=1>

US- CMS/ Payor model used to reimbursement these products will be part of the EHR.

Product recalls, product shortages, inventory management, item master management and product substitutions Reducing Rental payments

Member hospitals have requested that major GPO's work with suppliers and regulatory agencies to further the adoption of a universal and unique identification system for medical devices. This would contribute positively to patient safety and operational efficiency.

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External Scope

Device Manufacturers

Top Six Sectors of the Medical Device and Supply Industry by Sales, 2002

088 2004- 320 Billion
14937 Manufacturers

Sector	Percentage
Suppliers	56%
Other	14%
Cardiovascular	14%
Diagnostics	3%
Ophthalmology	6%
Orthopedics	6%

Source: FactSet, Merrill Lynch
Note: Composite sales of 109 companies in the Merrill Lynch Medical Technology & Hospital supply Composite Index.

Naming Systems: Nomenclature

- There are **11 competing nomenclature systems** for the naming of medical devices
- There are **16-20 Medical Device Classifications taxonomies**
- There are roughly **20,000 Generic Device Groups**
- FDA currently lists **80,000 brands and models** of medical devices used in homes, physician's and dental offices, and hospitals
- This FDA listing, multiple sizes of product (e.g., a 100-glove box and a 500-glove box) appear as one item, therefore, Itemization would yield an estimated **500,000 - 800,000 Device Types:**

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Current Manufacturer Process

The UPN (UPNs are found on approximately 70 percent of medical and surgical supplies) can be assigned by the Health Industry Business Communications Council (HIBCC) or the GS1 organization (formerly the Uniform Code Council (UCC)). Firms choose between HIBCC and GS1 based on what numbers they already use and where they plan to sell their products. After choosing the format, the firm must purchase a labeler identification code (HIBCC) (250K health product recorders) manufacturer's identification number (GS1). In addition to the labeler identification code or manufacturer's identification number, the UPN includes a manufacturer-assigned product number, a package-level code, and a check digit. Thus, each product is assigned a unique number at every packaging level, from bulk boxes to unit-of-use.

Other Numbering Systems:

Dun & Bradstreet's Data Universal Numbering System (DUNS) Number, Uniform Code Council (UCC)/EAN International (EAN) Company Prefix, Allied Committee 135 Commercial Government Entity (CAGE) Code).

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A Hospital's Instrumentation Losses and Population

The average 200 bed hospital has:

- **15-20** Electronic Medical Devices per bed. GE Medical 2004
- ***Estimated 180 Medical Instruments Tools per bed** in a 200 bed hospital
 - Non electronic Instrument define as any medical tool or aid having a value above \$25.00
 - <http://www.fasttrackitd.com/reports.html#report1> Future adaptation of RFID to Healthcare, Pains-Sokol 2004
- **334 Supplies per bed** (more field study proof needed for verification: Brad Sokol 9-06)
 - Any medical supply aiding the healthcare process having a value above \$2.00 and less than \$25.00
 - The CSSD manager of UKT (Germany) :
 - "The UKT has about 1500 beds and in all disciplines about 300 000 instruments from more than 20 different manufacturers."http://www.medicin.uni-tuebingen.de/Kliniken/haut_ki/index.html

Hospital's Lost Cost of Medical Tools a Year:

- An average of **10-30%** of the instruments are **replaced a year** (due to usage and theft).
 - SURGICAL INSTRUMENT MANAGEMENT REDUCES SURGERY DELAYS AND DRIVES STAFF PRODUCTIVITY: 2005 COMPUTERWORLD HONORS CASE STUDY 4-11-2005
- **5% to 15%** of hospital inventory is **written off each year**
 - Frost & Sullivan
- A **hospital can lose nearly \$500K-\$1 million a year** in medical equipment thefts.
 - hcPro Healthcare Marketplace
 - Material Management in Healthcare

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Commonwealth Fund report gives U.S. health care system poor marks

<http://d04.webmail.aol.com/19939/aol/en-us/Mail/display-message-body.aspx?folder=New%20Mail&uid=1.15110082&user=3sKuN7IRJ1#1>

The U.S. health care system lags far behind what it could achieve in terms of quality, access, equity and efficiency, according to a [report](#) released by a Commonwealth Fund commission. The commission compared the U.S. health care system with 18 other industrialized countries on 37 indicators and gave it an overall score of 66 out of 100, with average U.S. scores ranging from 51 for efficiency to 71 for quality and equity. The authors estimate the country could save from 100,000 to 150,000 lives and \$50 billion to \$100 billion each year by closing the gap between actual and achievable performance in each of the rated areas. Carmela Coyle, AHA senior vice president for policy, said that while the U.S. has some of the best nurses, doctors and technology, the report "underscores a problem America's hospitals know well: the need for broad-based reform of our health care system."

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Cost of Healthcare-Associated Infections

Cost of Healthcare-Associated Infections in a 300 bed hospital	Cost Per Infection	System Wide Results
15 % of HAI's are preventable through better process protocol in decontamination of surgical instruments: Feb 2001 Report to Scottish dept of health working group: www.decontamination.nhs.uk	\$4.5 to \$5.7 billion in healthcare: Burke JP. Infection control - a problem for patient safety. <i>NEJM</i> 2003; 348: 651-656 and three other sources: http://www.ssn.com/hr/DADAazine/hc_rfid.html ; <i>American Journal of Epidemiology</i> Vol 159, No. 4, 2004	Estimated 2 million hospital-acquired HAI occur each year in the United States. Accounting for an estimated 90,000 deaths Burke JP. Infection control - a problem for patient safety. <i>NEJM</i> 2003; 348: 651-656
Avg. length of stay of 11.8 days	A single hospital infection is estimated to add \$38,600- \$58,000 http://www.infectioncontrol.com/articles/448.html	7 states in the past 2 years. 10 expected to pass in 2006. 15 more considering legislation by 2008 http://www.apic.org/Content/NavigationMenu/GovernmentAdvocacy/
Direct Costs for each infected patient	\$3600.00 www.HCProject.com Verified by three additional sources: UK study.	Infection program cost 250K; Hospital savings annually 900K- Benefit \$650K
Wound infections - 57%	\$3,000-\$27,000; 6 additional days <small>Cost and Cost Benefit of Infection Control: William K. Greene, Ph.D., M.P.H.; David J. Moran, M.D., M.P.H.; Hospital Epidemiology, UNC Health Care System © 05</small>	MedSun- "Best" Database 350 Hospitals (MAUDE)-FDA Manufacturer and User Facility Device Experience ECRI Alerts Tracker/ Nat .HC Safety Network
Sternal (sternum) wound infections- % included in above number	\$20,000-\$80,000- 8 days	CANADA: \$281 Million for 2006 US: equivalent: 3 Billion- (\$11 mil 2006)
Catheter-associated bloodstream infection - 17%	\$5,000-\$34,000- 5 days	12%--25% Mortality for each infection http://www.cdc.gov/nczod/diseases/zoonotic/diseases/ai/ai.htm
Pneumonia- 26%	\$10,000-\$29,000- 5days	4.3% in 1981-1986 to 58.9% in 1993-1998
Urinary- 10%	\$700- 2 Days	MRSA: http://www.cdc.gov/nczod/diseases/zoonotic/diseases/ai/ai.htm
Single Use Devices	Reused 11% -19% of the time	<small>A Road Map to Medical Device and Instrumentation Pedigree</small>

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CDC- National Healthcare Safety Network
Replaces 3 databases

U.S. hospital discharges and spending on major chronic illnesses

	2004 U.S. afflicted	2004 U.S. discharges	2004 U.S. in-patient cost	2004 Medicare discharges	2004 Medicare cost per discharge	2004 Medicare in-patient cost
Coronary artery disease	13 million	1.6 million	\$39.6 billion	.9 million	\$29,000	\$25.6 billion
Heart failure	5.2 million	1.2 million	\$19.8 billion	.8 million	\$19,000	\$15.2 billion
Chronic obstructive pulmonary disease	8.6 million	.6 million	\$8.2 billion	.4 million	\$16,000	\$6.2 billion
Mental health disorders	20.4 million	1.0 million	\$11.4 billion	.2 million	\$16,000	\$3.9 billion
Diabetes	17.6 million	.5 million	\$7.4 billion	.2 million	\$20,000	\$3.8 billion
Hypertension	51.1 million	.2 million	\$4.6 billion	.1 million	\$22,000	\$3.2 billion
Asthma	20.7 million	.4 million	\$3.3 billion	.07 million	\$13,000	\$1 billion
TOTAL	(a)	5.5 million(b)	\$94.3 billion(b)	2.8 million(b)	\$21,000(b)	\$58.8 billion(b)
Percentage of 2004 Medicare spending						19%

Source: estimates based on 2001 hospital discharge and cost data from the Agency for Health Quality Research, Healthcare Cost and Utilization Project¹ (a) Number of afflicted does not total due to co-morbid conditions. (b) May not total due to rounding.

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Medical Device Pedigree

"Medical tools enabled with a standardized naming system, interoperable databases and communication technologies that could be used to authenticate, monitor, report and track a particular instrument's history relative to a rules based event cycle, involving workflow, maintenance, sterilization, procedure, adverse event, and all elements linking a patient's procedure, achieving maximum utilization and security throughout the device's event life cycle in a closed (Hospital) and open loop supply chain."

- **Linking medical tools to maintenance, sterilization, procedures and the patient will yield a reduction in infections and increased efficiencies.**
- **A "Universal Translator" (Nomenclature Sequencer Code) will integrate global semantics into a unified interoperable relational standard enabling Medical Device Pedigree.**
- **Provide "Confidentiality, Integrity and Authentication."**
- **"The 8 L's"**
 - **Last Manufacturer, Last Maintenance, Last Sterilization, Last Instrument, Last Location, Last User, Last Procedure, Last Patient**

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In the UK a **Specification for Surgical Instrument Management (Tracking & Traceability)**, by the NHS Estates and a number of organizations, the Medical Royal Colleges, the Association of British Healthcare Industry is currently in development.

- Model Engineering Specifications for Benchtop Sterilizers (C15) and Washer-Disinfectors (C31);
- a Specification for Validation and Maintenance Services for Decontamination Equipment.

Source: Healthcare associated infections – a guide for healthcare professionals Board of science 2-06: ISBN: 1-905545-02-9 , THE DECONTAMINATION OF SURGICAL INSTRUMENTS IN THE NHS IN ENGLAND – UPDATE REPORT: "A STEP CHANGE" © Crown copyright 2005

It is presently difficult to "tag" individual surgical instruments, as instrument sized labels do not survive long because of the sterilization process, and etching will invalidate warranties on many instruments, and all are potential hiding places for infection.

RFID-tagging (Radio Frequency Identification tagging) is in theory an ideal solution for tagging individual instruments. In an industrial environment, a whole pallet of goods can be "read" in one pass through an RFID-reader, but for surgical instruments, costs are presently very high, and the tags that would survive the temperatures in a SSD would have to pass very close to an RFID-reader.

Thus the call for individual instrument tracking is some way from becoming reality for all SSDs. (Sterile Services Department)

<http://www.medicalnewstoday.com/medicalnews.php?newsid=21578>

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Why do we need a Medical Device Pedigree?

- Currently, the medical tool industry **doesn't have** the a standard global nomenclature or global data number assigned to each tool.
- There is a **serious public risk**, without the medical tool *"Data Provenance"* to nomenclature and interoperability.
- The risk is exponential when considering the **lack of informatic tools** to connect and address nomenclature, patient records, infection control, sterilization verification, reprocessing and supply chain pedigree challenges.

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40 million persons hospitalized annually in US; 5% or 2 million will develop a HAI

Morbidity and mortality (90,000 deaths)

Variable prolongation of hospital stay

Total annual hospital-related financial burden-\$6.5 billion

Source: Cost and Cost Benefit of Infection Control, William A. Rutala, Ph.D., M.P.H.

David J. Weber, M.D., M.P.H., Hospital Epidemiology, UNC Health Care System, December 2005

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Why do we need a Medical Device Pedigree?

- **Substantiating the relationship between the impact that medical tools have on infection mortalities and patient safety, will permit us to control and reduce the exposure by which infections are transmitted, causing unwarranted mortalities.**
- **My estimates suggest that 13,000-26,000 mortalities could be prevent in the US a year by developing a pedigree model for medical tools in the healthcare Micro and Macro supply chain. The above estimates also include resulting infections after a patient is released from a medical care facility. 20% additional HAI's after discharge****UIC Epidemiologist Confirmed as a possibility. (100 + Medical Journal Reports, 60 + reported news events covering the past 15 years) Am J Infect Control. 1992 Aug;20(4):208-13. Post discharge surveillance for nosocomial wound infection: a brief review and commentary. Holtz TH, Wenzel RP.**
- **Unfortunately, the above relationship may not prove economically efficacious until a catastrophic disease outbreak makes Medical Device Pedigree a global humanitarian concern.**

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22,076 a year: # Potentially Avoidable Deaths* Associated with Excess Patient Safety Incidents Among All Non- Distinguished Hospitals

Third Annual Patient Safety in American Hospitals Report 4-2006 Zhan C and Miller MR. Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization. JAMA. 2003; 290(14):1868-1874

The National Audit Office (Report by the Comptroller and Auditor General – HC 876 session 2003-2004). *Improving patient care by reducing the risk of hospital acquired infection: a progress report*. London: NAO, 14 July 2004

The FDA estimates that problems with medical devices result in 300,000 deaths and injuries annually as reported by the Boston Globe. (Kerber, *Boston Globe*, 7/14/05) <http://www.medicalnewstoday.com/medicalnews.php?newsid=27451&nfid=rssfeeds>

1996 Apr;173(4):963-70

Surgical site infections occurring after hospital discharge.
Sands K, Vineyard G, Platt R.

Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts, USA.

In a study of 5572 people 139 acquired an SSI. Of the 139 - 84% of SSI occurred after hospital discharge: These data suggest that most SSIs occur after discharge and are not detectable by conventional surveillance. Nonetheless, they cause substantial resource utilization.

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Where are we Today?

There are no plans to include Medical Instruments or Supplies in today's Global Healthcare Interoperability Models

Current Business Problem

- Point-to-Point Interfaces
- Mappings are a Time Consuming and Expensive Process
- Lack Consistent Naming Convention
- Lack Standard Data Names
- Expensive System Integration
- Data Normalization
- Match & Validate
- Stds Compliance
- Verify Access
- Supply chain inefficiency- Redundancy
- Ill-equipped Legacy Systems

30 Gov. Databases

45 Databases

Excessive cost, complexity and time

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There are commercially available private models for instrumentation and supplies that can enable and be integrated into the healthcare interoperability model.

3M

IBM "EPCIS Pilot"

UPMC

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Solution Components

Mobile Domain

Real Time

Multi-Network

Data Collection

Hand Held

Nomenclature Domain

- Nomenclature Repositories
- NSS
- Procedure Registries
- Adverse Event Registries
- Infection Registries

Applications Domain

- ERP
- WMS
- SCM
- Logistics
- Patient Registry

Integration Domain

- Messaging
- EAI
- B2B

Pedigree Infrastructure Software Domain

- Rules & Events
- Data Management
- Associations
- Device Mgt
- Filtering

Hardware Domain

- RFID
- Barcode Scanners
- Reader
- Printers
- Healthcare Facility

Global Data Synch

- Dynamic NSS
- SNOMED
- HL7
- GTIN

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HIMSS Conference Call

1. Lack of information about which patients were treated with devices
2. Can't Locate, Recall Notices "lost" to wrong person
3. Devices left in Patients, Implanting incorrect devices, Use Err.
4. MDR (Medical Device Record) lacks details i.e. model number, Lack of information about which patients where treated with devices
5. Insufficient data available for all areas of supply chain
6. Supply chain has no means to identify this problem
7. Medical facilities can't assure total sterility, problem worse for smaller out patient clinics and cold sterilization practices
8. Device maintenance - cases where infections have been passed from patient to patient due to improper device maintenance

Potential Classifications of Medical Devices Relative to UDI Needs

Prospective Device Classification/Subclass	Potential Importance of UDI	Existing Level of ID/Tracking	Comments
Implantables			
Permanent	High	Adequate	Currently powered devices are identified and tracked
Temporary	High	Adequate	Currently powered devices are identified and tracked
Non-active	Moderate	Not known	Some devices are individually identified and tracked
Accessories or non-active components	High	Inadequate	Evolving technical issue; UDI role might change or be case-specific
Device materials [a]	High	Adequate	Systems other than UDI (e.g., labeling) generally used
Capital assets			
Laboratory	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
Non-invasive	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
Invasive or life-support items	High	Inadequate	Occasional problems in tracking have occurred
In vitro diagnostics	Moderate	Adequate	In-hospital tracking covered by maintenance and inventory controls
High-risk devices (Risk to patient)	Varies with risk	Varies with risk	FDA's Class III devices are of greatest concern
Infectious Risk/Sterility	High	Sometimes inadequate	Concerns have arisen with inadequately cleaned devices
Supplies (Disposables)	Varies	Varies	Disposability might be described in UDI database
Single-use only	Varies	Varies	Single-use feature might be described in UDI database
Reprocessed devices	Varies	Often inadequate	Tracking might require further labeling by reprocessing firm
Reusable devices	Varies	Varies	Reusable feature might be described in UDI database
Interoperability [b]	Varies	Varies	Depending upon issues, might pose problems for UDI
Care setting	Varies	Varies	Uncertain applicability to UDI database
User of device	Varies	Varies	Uncertain applicability to UDI database
Kits vs. components	Moderate	Varies	Characteristics might be addressed in UDI database
Systems vs. components	Moderate	Varies	Characteristics might be addressed in UDI database
Devices requiring expiration dates	Varies	Varies	Device expiration dates would be addressed in UDI database
Devices relating to bioterrorism	Varies	Varies	Characteristics relevant to bioterrorism could be addressed in UDI database

Source: ERG, 2005.

[a] Materials that are allergenic or other have other properties relevant to patient safety (e.g., latex).

[b] Includes mechanical, electrical, and software interoperability.

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Nomenclature Sequence Code and Registration Authority Service

Nomenclature Sequence Code: NSC
A rules based metadata naming system; master code (*universal translator*) that combines similar data concepts in different language formats. When the language formats' data element's have been mapped to the NSC, A unique data element can be assigned to the NSC, The NSCs' data element can than point to multiple historical events within the community of database langue formats.

The diagram illustrates the flow of information from external data to a registered name. On the left, 'Nomenclature 1' includes 'External Stethoscope', 'Conceptual Digital', and 'Physical Loc.' with a grid below. On the right, 'Nomenclature 2' includes the same categories. Arrows from both point to a central box labeled 'Nomenclature Sequence Code'. An arrow from this central box points to a top box labeled 'Registration Authority Registered Name'.

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Part of Graphic Source: An Introduction to the Universal Data Element Framework
September 6, 2006 - The Open Group: Ron Schuldt, Chair
Adapted by Brad Sokal 9-9-2006

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September 21, 2006
A Road Map to Medical Device and Instrumentation Pedigree

Example of "Business Function" categories for Surgical Scissors Commodity

Segment:	42 00 00 00	Medical Equipment Supplies & Accessories
Family:	42 29 00 00	Surgical Products
Class:	42 29 16 00	Surgical Cutting Instruments & Related Products
Commodity:	42 29 16 14	Surgical Scissors

↳

Extensions:	42291614-01	Surgical Scissors – Bandage
	42291614-02	Surgical Scissors – Delicate
	42291614-03	Surgical Scissors – Dissecting

The Physical Markup Language (PML) will be based on HL7.

The PML should include extensions for recording pedigree information, returns, recalls, adverse events as well as the procedures performed with the device and instrument.

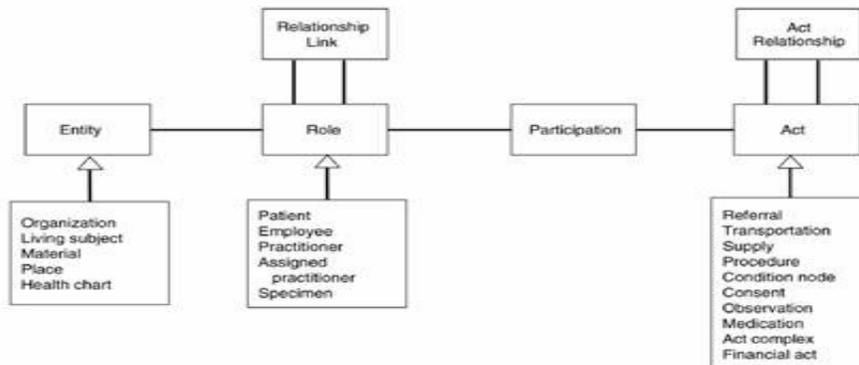
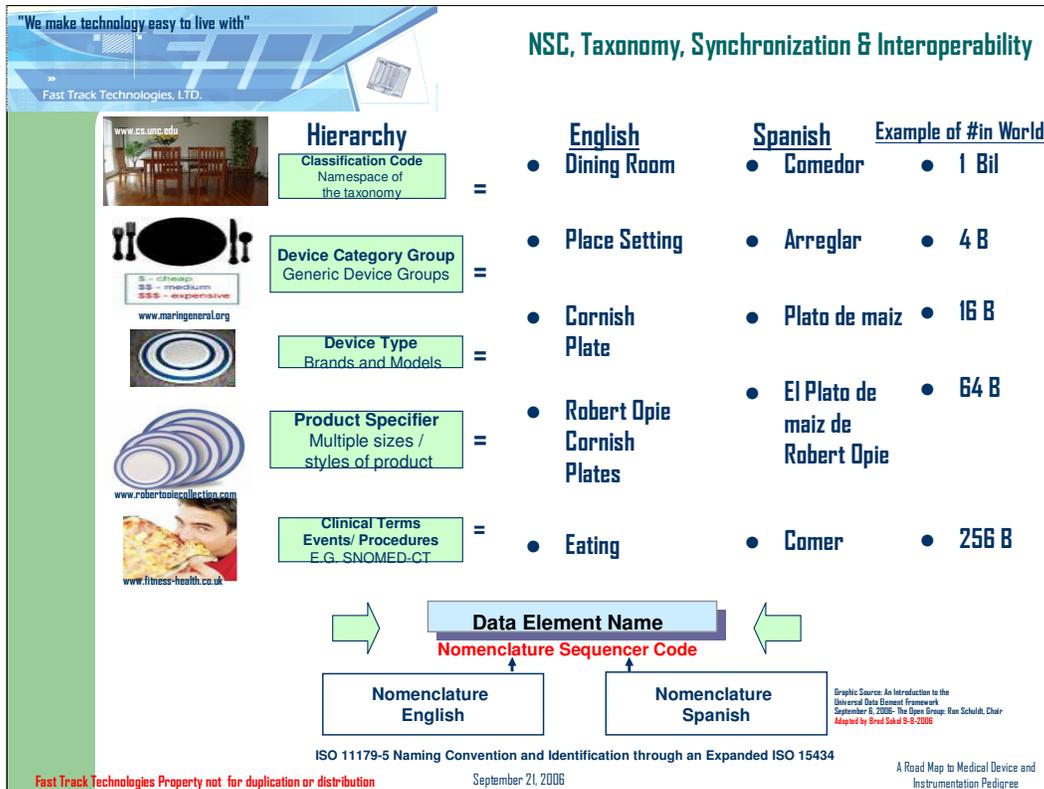


Figure 4-1. HL7 reference information model.

SOURCE: Hammond (2002).



5 Level Logical Hierarchy 15 digit code

There are Globally 11 Nomenclature databases of which 5 are in the private sector :

First Layer- Classification Code Layer: 16-20 Medical Device Classification taxonomies: Category code (2 digits).

Second Layer- Parent Layer – Device Category Groups: Roughly 20,000 Generic Device Groups: Generic device group code (4 digits).

Third Layer- Child Layer –Device Type Term : FDA currently lists **80,000 brands and models** of medical devices used in homes, physician's and dental offices, and hospitals from approximately 11,500 medical tool manufacturers.

Device Type group code (4 digits).

Forth Layer-Child Layer- Product Specifier /Preferred/Template/ Synonym Terms: The FDA lists multiple sizes of product (e.g., a 100-glove box and a 500-glove box) appear as one item, therefore, Itemization would yield an estimated **500,000 – 800,000 Device Types: Product Specifier code(5 digits)**

SNOMED - Fifth Layer- Clinical Terms- CT

Over 366,170 procedural concepts- formal logic based definitions organized into hierarchies.

These contain more than 993,000 English language descriptions, synonyms

Having an additional 1.46 million semantic relationships.

Infection Database Scope:

6 government agencies involved with 20 databases.

5 private sector subsets

27 categories in which HAI are classified.

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Current Point-to-Point Approach

Excessive cost, complexity and time

Medical Semantics Standard Approach

Nomenclature Sequence Server

Nom 1, Nom 2, Nom 3, ..., nom n

Nomenclature Sequence Code =

Map-to-NSC Approach

Nomenclature Sequence Server

NSC Name

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How Tag Data is Read

How to read the EPC memory

All readers have an INVENTORY command to automatically read the EPC data and verify that the data was received correctly. However, if you wanted to read the EPC manually, you would follow this procedure. This gives you an idea of how to read from other memory banks as well.

Select the EPC memory bank (bank 01).

Read 6 words (96 bits) starting at word 2. Gen 2 tags always read 16-bit words, not 8-bit bytes.

Calculate a CRC on the data you received.

Read 1 word from the EPC memory starting at word 0. This is the CRC that was calculated by the tag.

If the calculated CRC matches the tag's CRC, the EPC data is valid and can be used.

Gen 2 Access Commands

File Config Help

Read

Memory Bank: EPC(01) | Word To Read From: 2 | # of Words To Read: 6 | Read Tag Memory

Write

Memory Bank: EPC(01) | First Word To Write: 1 | # of Words To Write: 7 | Write Tag Memory

Options

Use BlockWrite

Lock Options

Perma-Lock Pwd write
 Perma-Lock 2 Pwd write 2

Data To Write: 0102 0304 0506 0708 0910 1112 1314 1516 1

Lock

Kill Pwd | TID Memory Pwd write
 Perma-Lock Pwd write | Perma-Lock Pwd write

Access Pwd

Perma-Lock Pwd write | User Memory Pwd write

EPC Memory

Perma-Lock Pwd write | Lock Tag Memory

Erase

Memory Bank: EPC(01) | Word To Read From: 0 | # of Words To Erase: 6 | Erase Tag Memory

Kill

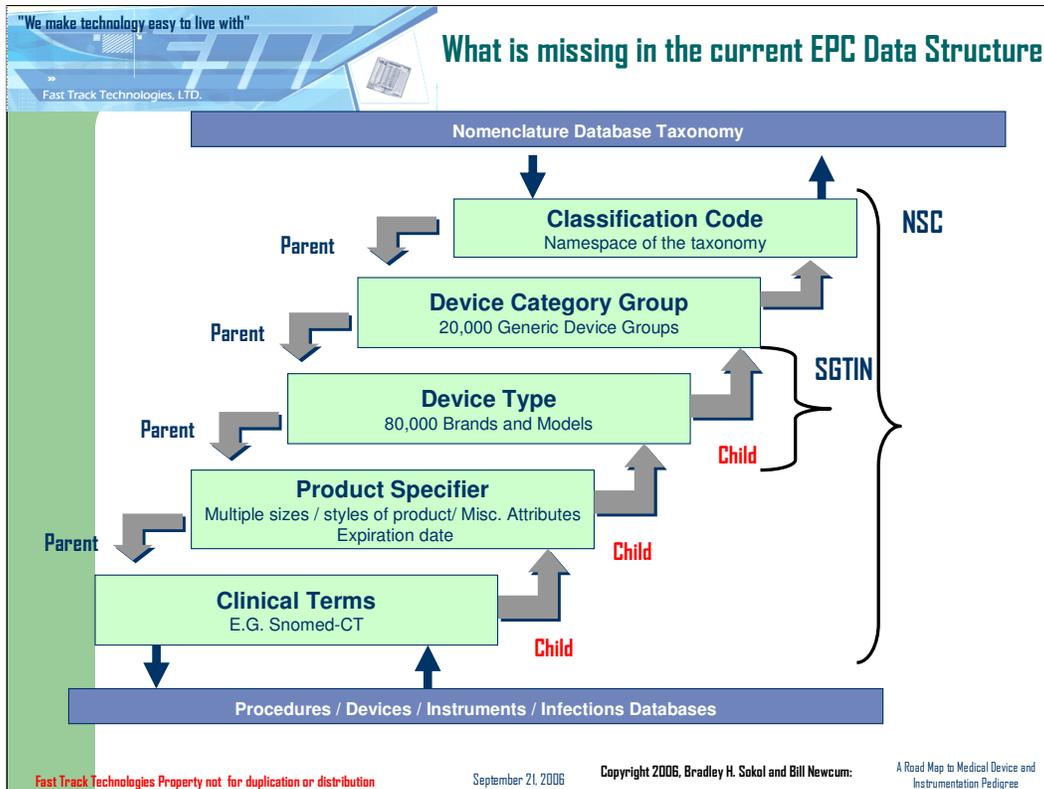
Kill Password | Kill Tag

Access Password:

Status / Results

Tag Found:

ID: 30 18 78 90 2F F8 98 00 00 00 10
Data: 30 18 78 90 2F F8 98 00 00 00 10



How to read user memory

Select the user memory bank (bank 11).

Read 8 words (128 bits) starting at word 0. This reads all 128 bits.

There is no CRC verification of this data. If you need CRC verification, you have to embed a CRC into the data stored in the user memory.

Alternately

If you want to read just a portion of user memory, say the ordinal expiration date in bits 64 – 79, then you can read one word (16 bits) starting at word 4 (bit 64).

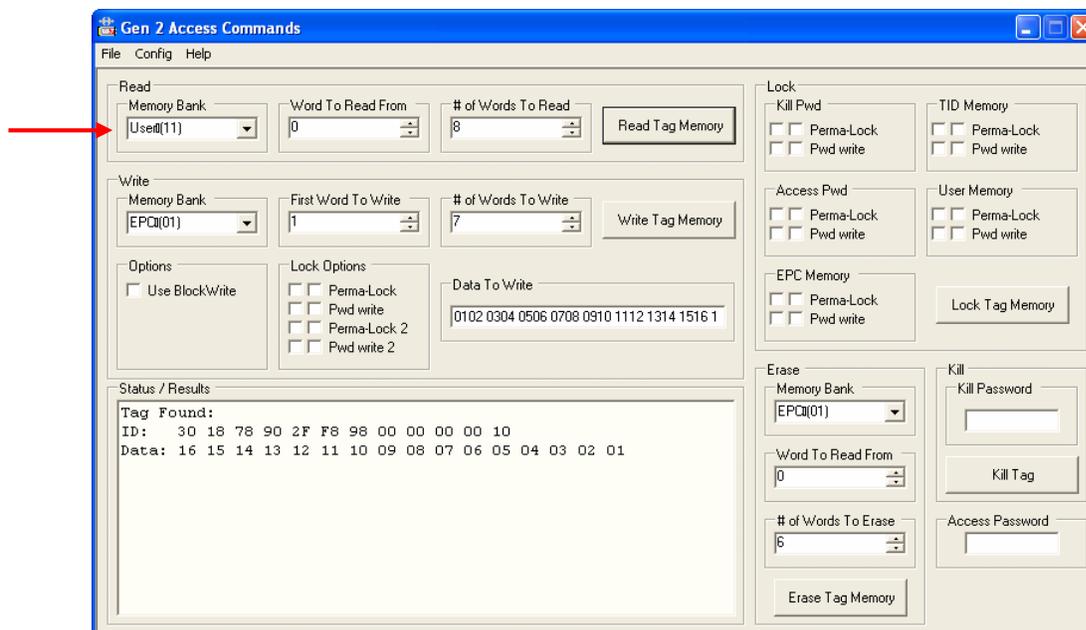
Changing Bits

You can also write to a single word to the user memory. So if you need to change one of the four bits used for sterilization, then:

Read the first 16 bits in the user memory

Alter one of the four bits.

Write the modified 16 bits back to the first word in user memory.



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Some Core Attributes

Tag Data Elements

1. Manufacturer (from UPN- EPC)
2. Make, Model (from UPN-EPC)
3. Company generic model name
4. Version, especially software (needed for device remote maintenance)
5. Models within version
6. Serial Number
7. Original Equipment Manufacturer vs. the Distributor
8. Labeler (use the GSI or UPN definition) HIBCC - Healthcare bar code (medical/surgical & devices)
9. Places of Manufacturer (this can be more than one)
10. Date of Manufacturer
11. User Memory pointing to Nomenclature Sequence Server (NSS)
 - NSC
 - Ordinal date
 - Miscellaneous code
 - Optional Serial Number for Closed-Loop Applications

Nomenclature Database Component queries

1. Distributor
2. Contract Manufacturer
3. Number of uses allowed (reprocessing etc)
4. Number of uses so far
5. Expiration date
6. Component, Kit, Parent/Child Relationship
7. FDA Approval or marketing basis (Good Practice Marketing)
8. Reimbursement Approval
9. Adverse event reporting (history)
10. Regulatory Compliance
 - Software compliance: Date of last update and by whom
 - Maintenance compliance, post-approval
 - Safety alarmed compliance
11. Reprocessing Returns & Recall Management
12. Service and Warranty Authorizations Maintenance
13. Clinical attributes? (silicone, latex etc?)
14. Device may contain patient identifiable information (Y/N)
15. SNOMED procedural nomenclature, clinical term (CT), must be tied to patient's episode and procedure

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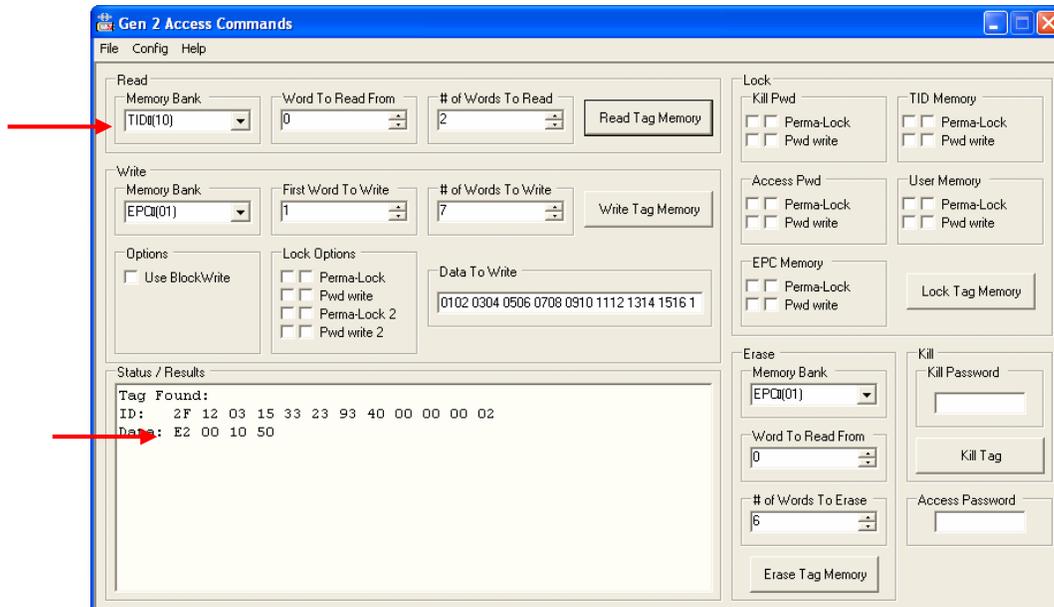
How Do You Know If There Is User Memory?

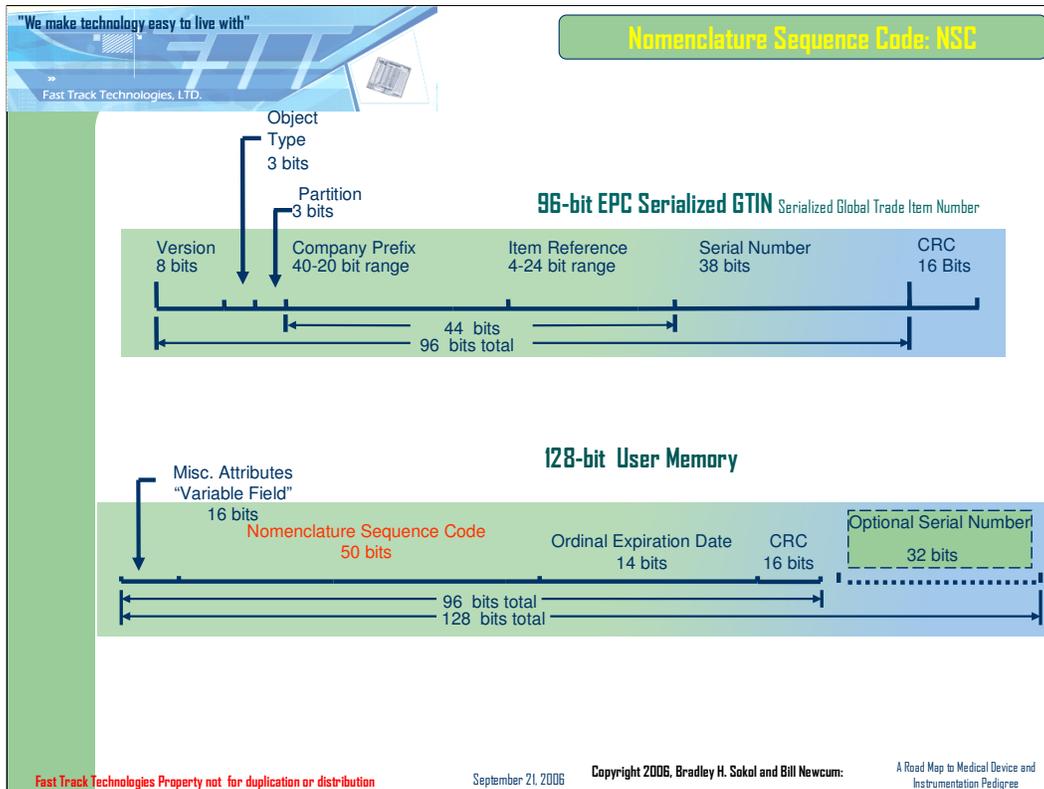
All Gen 2 tags have another memory bank called TID. This contains the manufacturer's code and a model code. Essentially this identifies the particular version of the silicon that is used in the tag. You can use this to identify the chip manufacturer and the features that are supported by that chip.

For instance, the standard Alien squiggle tag with Impinj silicon has a TID of E2 00 10 50. Most other manufacturers also use the Impinj silicon and will have the same TID. Any chip with this TID does not have any user memory.

The Philips tag with 128 bits of user memory has a TID of E2 00 60 01.

So it may be helpful to check the TID of a chip before trying to read or write the user memory.





Formulas for Calculating the Number of Bits

Numerical Data

$B = \text{number} / \log(2)$, rounded up to the next whole number

B is the number of bits used to store the number

Alpha-Numeric Data

$B = \text{num_characters} * 8$ (for 8-bit ASCII characters)

$B = \text{num_characters} * 7$ (for 7-bit ASCII characters)

$B = \text{num_characters} * 6$ (for old mod-50 characters)

EPC UHF Generation 2 (C1G2) Class 1 G2 - 128/256 bits

Gen 2 provides expanded data functionality and better performance, is designed to support EPC codes up to 256 bits long, and has the provision for extra data to be carried in the tag based on a single RFID protocol.

Items that are in the EPC SGTIN portion of the tag:

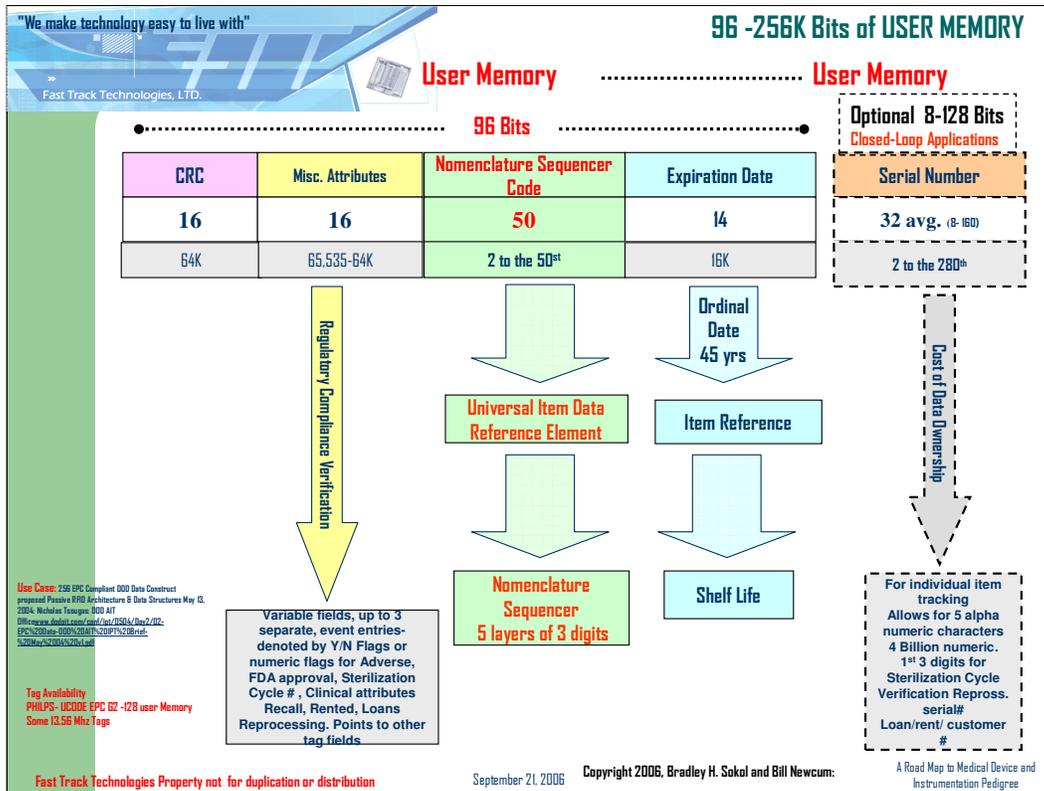
Company Prefix: (This is the shipping company, not necessarily the manufacturer)

Item reference

Serial number: (This is the tracking number of the box, or, in the case of Unique Device Identifiers, a tracking number for the device.)

The item reference and serial number typically refer to the shipping container, not the item in the container. If a device is repackaged in the supply chain, a different serial number and possibly a different item number are encoded in the RFID tag. New box. Then new tag and new serial number. The RFID tag acts like a sophisticated UPS tacking label that is designed to track the box, not the item.

The exception to this rule is when an RFID tag is attached to an item for the duration of its life. In this case the serial number represents an all-numeric pseudo serial number of the item. It is a permanent sequential number for a particular item type. In this case, it is a tracking number for the individual item. It need not be the manufacturer's serial number as these are often alpha-numeric identifiers.



USER Memory: Items that should be in the user memory of the RFID tag (password protected):

Misc Attributes: is a variable field that can point to other fields on the tag: ie Adverse event reporting (Sterilization pending event- Incident)
 Clinical attributes? (silicon, latex etc?) Remanufacturing, Recall, Rental, Loaner.

Nomenclature Data Sequencer Code: Index into third-party service that has access to UPN, GMDN, UMDNS, UNSPSC and historical events for the device.

UPN (Universal Product Number. See <http://www.upnrepository.org/about.htm>)

GMDN term (Global Medical Device Nomenclature, 3 fields of 5-digit codes, see <http://www.gmdn.org/index.xalter>)

UMDNS (Universal Medical Device Nomenclature System, 5-digit code, see http://www.ecri.org/Products_and_Services/Products/UMDNS/Default.aspx)

UNSPSC (United Nations Standard Products and Services Code, 2 6-digit codes, see <http://www.unspsc.org/>)

Expiration Date

CRC (Cyclical Redundancy Check) (Validates user memory fields)

Optional Serial number (can be alpha-numeric)- Used in closed loop environments-Information can be pared before leaving closed loop. The first three digits of this field represent amount of cycles the instrument has incurred:

Fields and headers will be associated with and how it tags back to EPC:

Discovery services

ONS Services

Authentication Services

Access Control Services

Cost of Ownership- Chain of Custody

Public

Private

Protected

The NSC Nomenclature Sequencer Code

Functionality

Info available

Info is needed

Only incites a query from the previous Chain of Custody;

Cost of ownership

Security

The need for Data Cleaning- Cleansing

Criteria for IUID Equivalents

1. Must contain an enterprise identifier which is assigned by a registration or controlling authority
2. Must uniquely identify an individual item within an enterprise identifier, product or part number
3. Must have an existing Data Identifier (DI) or Application Identifier (AI)
4. Listed Data Identifier and Application Identifier Standard
5. Global Individual Asset Identifier (GIAI) EAN.UCC (AI:8004)
6. Global Returnable Asset Identifier (GRAI) EAN.UCC (AI: 8003)
7. **Matrix Using ISO 15434 Syntax to satisfy the IUID Requirement!**

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Nomenclature Sequence Server (NSS)

- A Secured De-Referenced Registry Database that receives and sends queries as prompted by the NSC.
- This server is the gateway clearinghouse conduit to several other highly classified and secure databases.
- It operates in a secured virtual black-box server environment using Privacy-Preserving Indexing (PPI) http://www.almaden.ibm.com/software/quest/Publications/papers/vldb03_ppi.pdf
- Assures Confidentiality, Integrity, Authentication and Publisher Anonymity

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NSC “that points to historical events for medical devices.”

NSS “environment using Privacy-Preserving Indexing (PPI)”.

NSS “Assures Confidentiality, Integrity, Authentication and Publisher Anonymity.”

Use Case

Emulate a New Multi-Million dollar industry

server-based medical device data service : (Sequences proprietary codes for communication queries)

Contain Approximately 260 proprietary medical device protocols

Companies: Datascope: Panorama and Duo, HEI: Link IT, Sensitron: Care Fusion, Capsule Technologie, Cain Medical

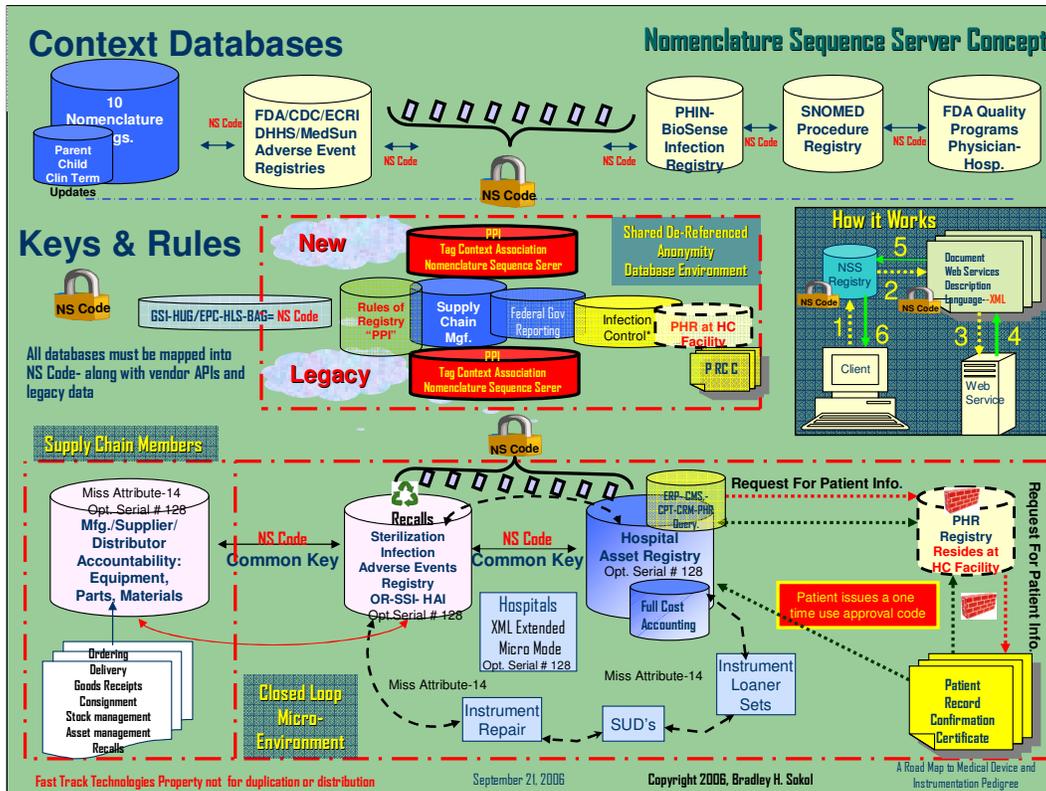
Estimated revenues in 2005 \$75-125 Million US Dollars

The above industry resulted from the disbandment of “Connectivity Interoperability Consortium”

<http://www.poct.fraunhofer.de/about/index.html>

Global healthcare Exchange Model

<http://home.ghx.com/UsingGHXMain.asp>



Simple Object Access Protocol is an XML based messaging protocol

SOAP- Message: well-formed XML document

Source: Intergovernmental Partnership Forum, June 16, 2003

Integrated Delivery Model

Rules

Query

Applications

Databases

Tables

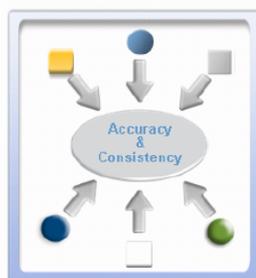
Catalogues

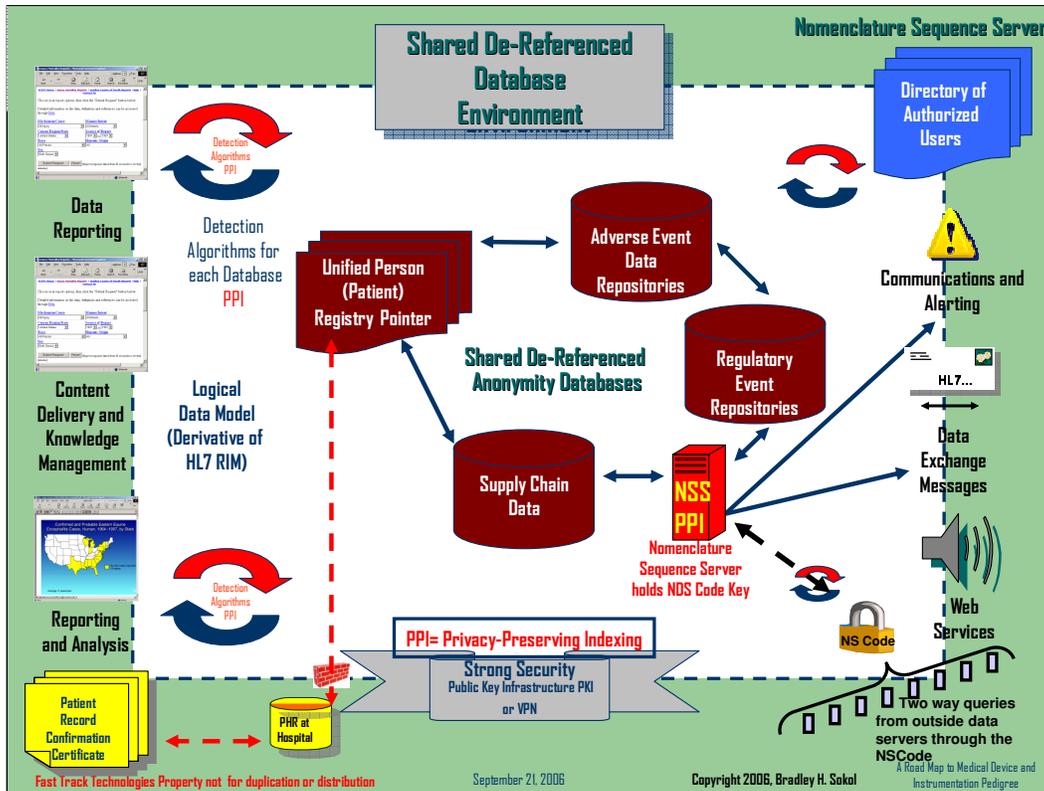
Spreadsheets

Files

Internal Synchronization

Data Cleansing





In the case of Patent Registry and Patient Record Information:

The Patient Record is kept at the HC Facility

A notification goes out to the patient record file and patient, anytime there is a request for information on the record.

The record can only be updated and accessed by the facility after the patient gives approval or the patient gives a directory of authorized users

The above applies to all government agencies inquiring in the patient record so that privacy issues are protected

Removal of Patient Identifiers in de-identified database: Protection of patient confidentiality by removal of personal identifiers from data sets is possible. An excessive concern in this area can remove so many potential identifiers, e.g. regional area of residence in the UK and hospital dates, that the data becomes of no value for research. The development of a concept of reasonable limitation where sufficient identifiers are removed to protect the subject broadly but not in such excess that no useful data remains would be helpful

The Patient Record Confirmation Certificate can be distributed by Windows mobile-Smart Phone 2005 (Built in certificate security)

Manufacturer de-identified database:

Manufacturer's of medical devices could also use the de-identified database concept allowing the public to view "near miss" events without fear of retribution.

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Returns & Recall Management & Service and Warranty Authorizations

Regulatory Compliance

- RFID tags satisfy traceability and MDR requirements.

Returns & Recall Management

- Supplement the basic shipment identification information by writing the specific customer and time of shipment to the tag immediately prior to distribution on the optional user memory field, providing several benefits.
 - In the event of a recall, companies could trace specific shipments to specific customers, which would enable a highly targeted notification and return operation and avoid a costly general recall.
 - For general returns, companies could verify that the customer returning merchandise is actually the customer who received it, which would deter diversion, counterfeiting and other forms of return fraud.

Service and Warranty Authorizations

- Authenticating the product and customer with proprietary information could also be used to authorize warranty and service work. A record of the activity performed could be kept in the Mgf. Database, the NSC and NSS could query the database and provide a complete maintenance history on the item.
- If future repairs or service are required, a technician could access the item's complete maintenance and configuration, by the NSC and the NSS pointing to the correct Mgf. maintenance database.

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Recycling medical devices raises concerns

Reusable medical devices were largely displaced by disposables when advances in plastic technology met the age of AIDS.

Hospitals are re-using single-use items multiple times, aided by industrial reprocessing companies. The practice slashes supply costs. Usually the devices work fine, but sometimes they don't, with disastrous results. A story *The New York Times* describes a heartbreaking case where a breathing tube tip damaged by reprocessing has permanently compromised a baby's ability to swallow. And the original makers won't warranty reprocessed devices, so the hospitals and the reprocessors are on the hook in any lawsuits.

In maintaining a device there are several mini-loops within the flow depending on where the item is repaired.

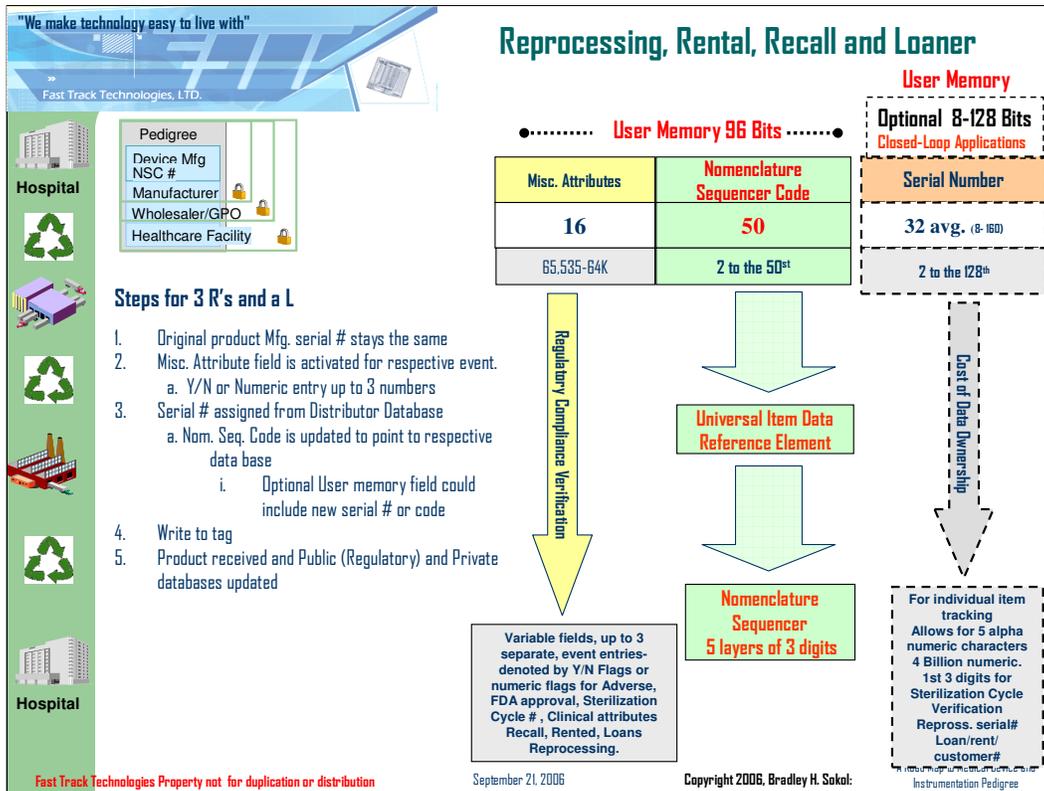
Maintenance Process: The maintenance process is very complex with numerous automation systems that place limitations on visibility at every level.

Logistics System tracking unit level maintenance

Installation Table of Distribution & Allowances tracks installation level maintenance, and

Depot System tracks depot maintenance.

Maintenance management at each level is difficult if the data in the automated systems is not correct or updated frequently.



The SGTIN uses the company prefix, item reference and serial number to create a unique ID. The company prefix and item number are essentially the common SKU that you see in retail applications. The serial number is a sequential number for the package, not necessarily for the asset in the package.

To track the physical asset, we can:

Use a UID similar to the DoD model.

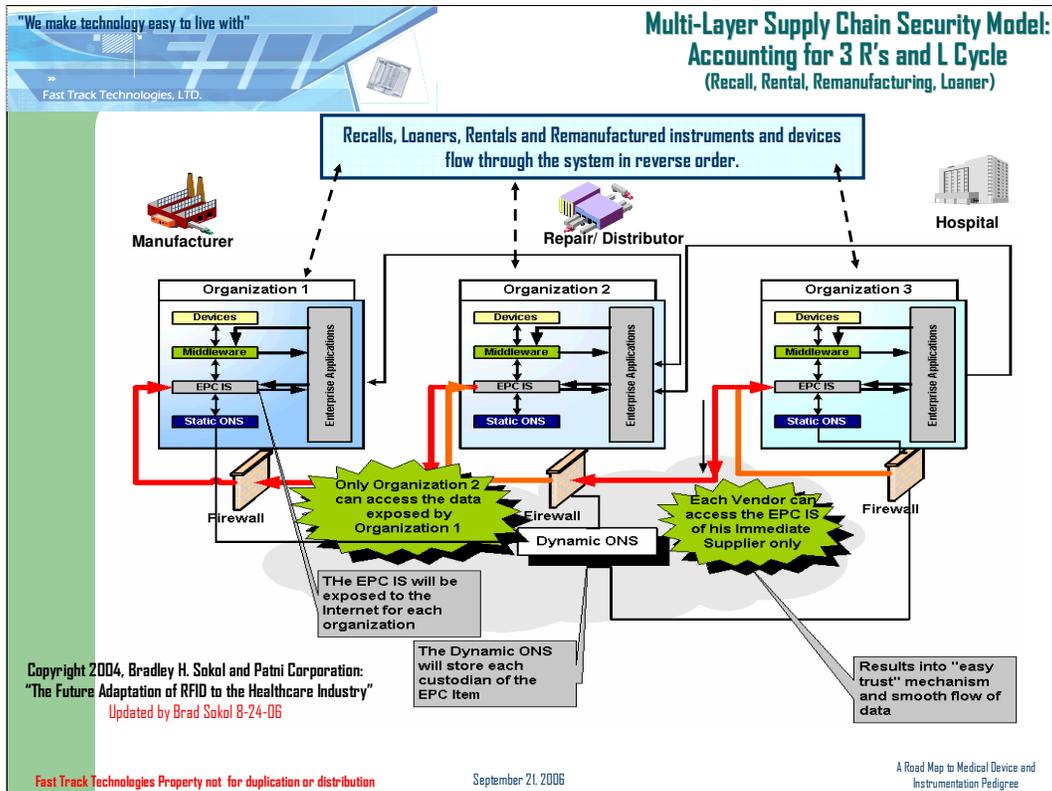
- A) Use ONS to lookup information about the manufacturer such as the asset's serial number. This system requires any distributor in the middle who relabels the box to enter the correct manufacturing information into the ONS in a timely manner.
- B) Build the UID information into the user memory that gets locked and never changes. That is what the serial number in the user memory is for. However, we don't have the manufacturer's information in the user memory. If we had more bits (on today's tags this can be done).
- C) The asset information must be built into the Asset Registry (the Internet of medical things). The asset registry must be flexible enough to record different IDs used at different times. i.e.

The manufacturer would have one ID for the asset, the distributor may have another, and the hospital may have a third. Some surgical instruments have a 2D barcode on them that can be used for this. 70 % of the instruments and devices today have tracking ID's . This asset number needs to be built into the user memory of the tag.

The tag on the packaging is a throw-away item. Once the device enters the closed-loop environment, then we have to depend on an embedded tag, or barcode, or a tag that is added after each sterilization. This is where the system the user memory applies. Either a 2D barcode or HP's memory spot will also work.

Middleware will initially provide closed loop tracking capabilities, until a hospitals enterprise system can incorporated the external model. a standard model

ERD (Entity Relationship Diagram) is too detailed to discuss at this point. A context diagram in would be the simplest way to rely the concept. We reserve the details for our non-disclosure relationships



This supply chain chart incorporates

1. Recalls
2. Rentals
3. Remanufactured
4. Loaners
5. Dynamic ONS is used with Events.

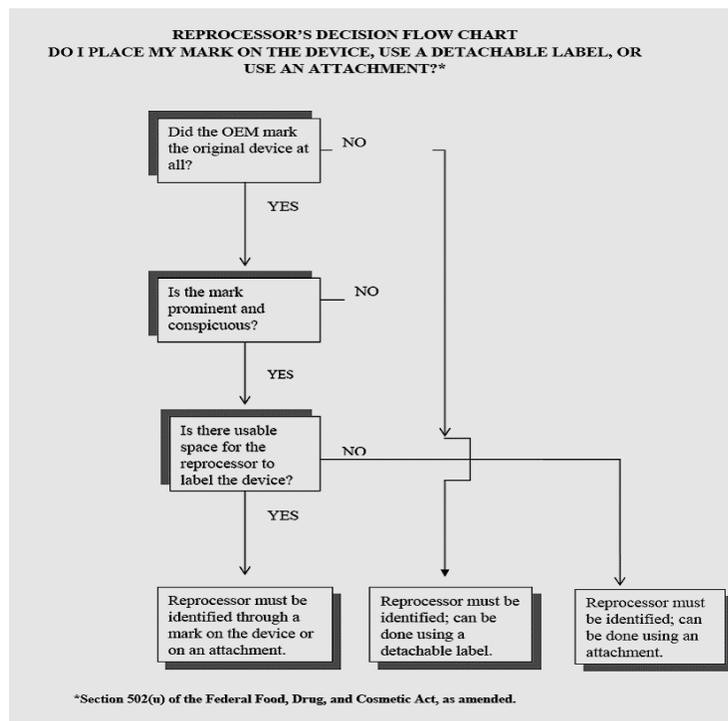
Legislative Support for MD&I

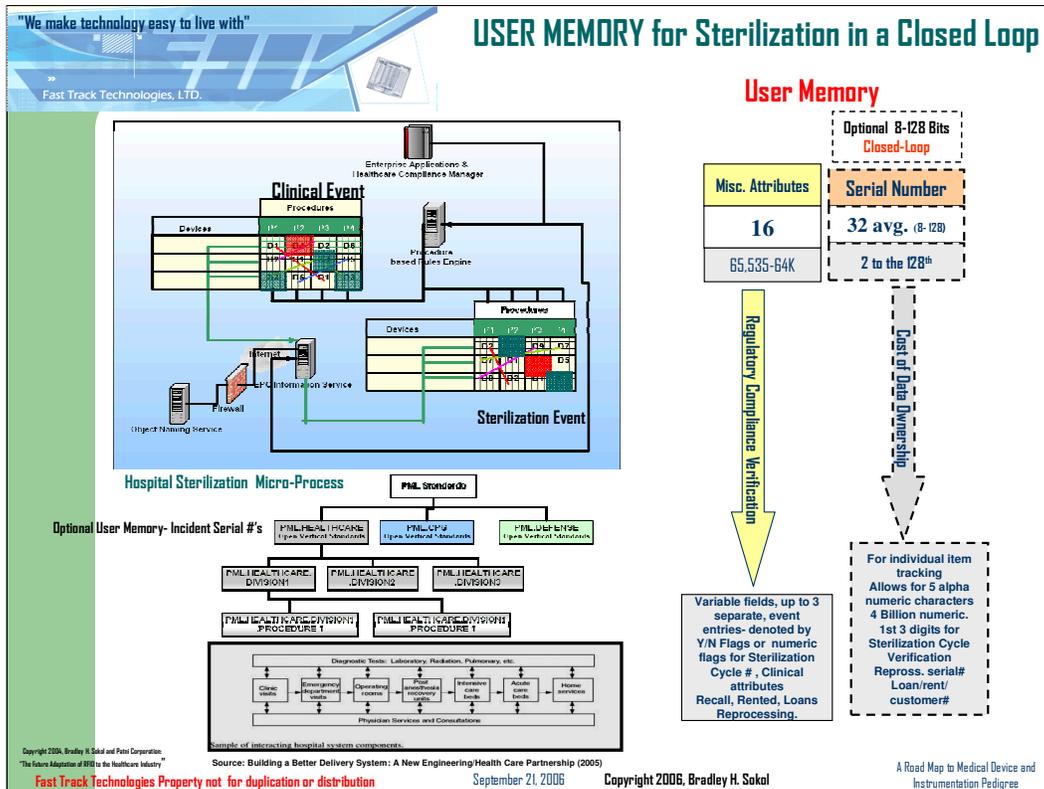
Utah Passed: Utah Senate Bill 110

Mass Passed: Patient Consent Law for Reprocessed SUD's Senate Bill 1321

8/23/2006: Sec 502c FDA Cosmetic Act: Reprocessors must indicate device repro with label.

Each step in the forward and reverse directions can repackage and re-label an item.





Methodology:

Instruments are scanned for ID, and tracked at the following points:

1. Entrance to system, by purchase or loan – where the item is coded and input into the information system
2. Inspection and packing for use in theatre, or for storage – where washing, disinfecting and sterilizing data can be added
3. Prior to use - if additional check required to confirm that specific instruments are used in a patient's operation
4. Exit from system.
5. The data is collated with Patient Record and Decontamination Record by Hospital Information System.

Case Study:

One of the more innovative uses of RFID today involves tracking and monitoring surgical equipment.

At **St. Vincent's Hospital (Birmingham, Ala.)**, surgical instruments are monitored to determine their location, last sterilization, maintenance record, and other key statistics. This technology can further identify individual surgical supply items and their purchase date, description, cost, and utilization data.

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128K Bits of USER MEMORY for Sterilization in a Closed Loop

User Memory

Misc. Attributes	Serial Number
16	32 avg.
65,535-64K	2 to the 128 th

Closed-Loop

A method for sterilization verification and pedigree tracking; using a passive tag

- Reader with controller getting info from autoclave conditions:
- Smart label with this autoclave sensitive material printed on it.

Basic system:

- Passive tag, read/write
- Reader/writer: reads and writes tags, 2-way communication with controller.
- Controller: acquiesces data from autoclave, makes decisions and puts data into a format, passes the data in the right format to the reader when the reader says "something is coming out, what should I write to it".
- Database: the database resides on a network and the controller feeds it information that the reader writes to the tag with time stamps, conditions, tag ID, etc
- Autoclave Mfg. could install a controller to streamline the process of data retrieval.
- The system can be made up of a PC, i/o cards for autoclave, i/o for reader/writer, and software for writing to a database.

Regulatory Compliance Verification

Variable fields, up to 3 separate, event entries - denoted by Y/N flags or numeric flags for Sterilization Cycle #, Recall, Rented, Leans Reprocessing.

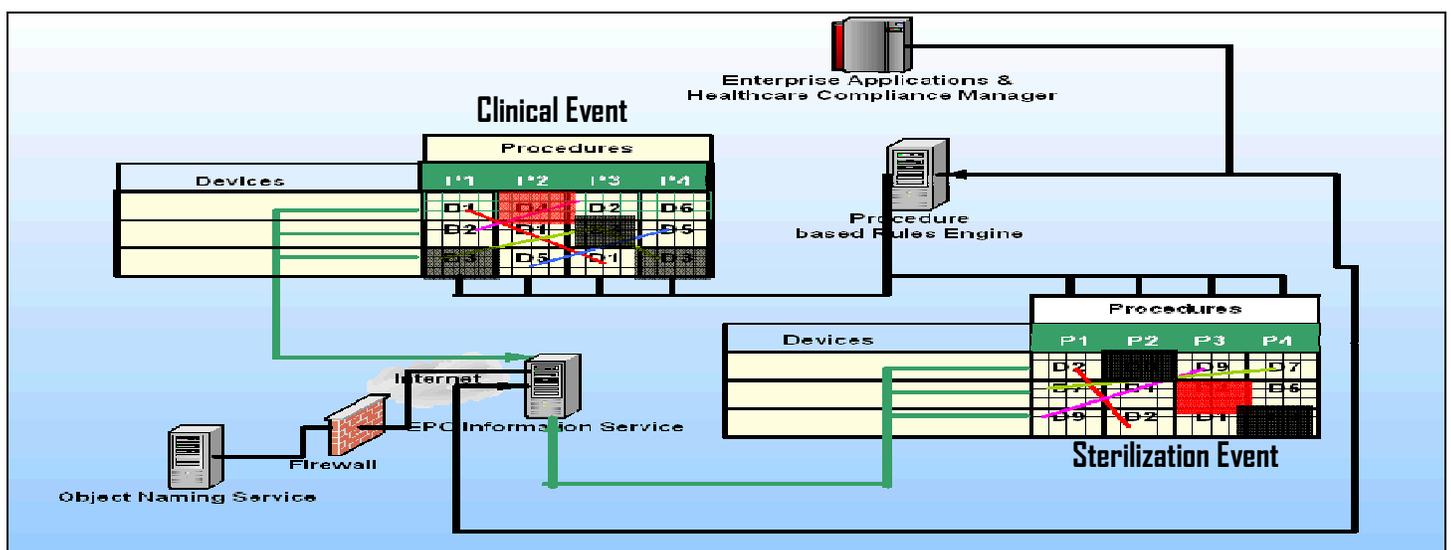
For individual item tracking
Allows for 5 alpha numeric characters
4 Billion numeric.
1st 3 digits for Sterilization Cycle Verify.

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Procedure:

- Each sterilization "batch" needs to be appropriately identified.
- Surgical instruments and devices are placed in trays, which are then sterilized using an autoclave machine.
- Once the items have been sterilized, the trays are assigned a batch number,
- The serial number on each instrument in the tray is related to this batch number.

This way, if an infection resulted from the surgical procedure, the instruments used in the procedure can be recalled for further examination and testing.



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Benefits for Sterilization in a Closed Loop

- **Autoclaving cycle counting.** The tag will have a built-in counter for counting the number of autoclave cycles the tag has undergone above a defined temperature threshold, overcoming the problems of the labor-intensive and error-prone manual tracking systems currently being used.
- **Tagging and monitoring of temperature sensitive products**
- **Compliance with regulatory requirements.**
- **Productivity Improvement**
- **Reduction in inventory on hand**
- **Reduction in working capital- improving profitability**
- **Sterilization verification**

Production of returned loan sets without RFID

With RFID

75% Productivity Improvement

0 hrs 2 hrs 4 hrs 8 hrs

Source: HIBCC Auto-ID Technical Committee 19 January 2006

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The only Healthcare/ ISO barcode methodology that could address 15% of the concerns that RFID tags do is the QR Code or the Datamatrix Barcode.

Unfortunately, the laser form factor on a medical device could become part of the infection problem.

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Instrument Tracking and Sterilization Solutions

Autoclave "Smart" Pressure Transmitter: Pressure transmitter is a microprocessor-based sensor specifically designed for sanitary fluid processes.

- <http://www.automatedsys.com/controls/claves.htm>
- <http://www.ellab.dk/Products/Medical/Probes.asp>
- <http://www.sk-automation.com/temperatureinstruments.html>

RFID -Surgical Instrument Tracking Hardware solutions

- The tag is a read/write type, which allows information on the decontamination cycle to be placed on the tag together with important data concerning the actual tracking of the set/instruments to the operating theatre/case. Unaffected by temperature and pressure, will stand up to all types of materials, will enhance the need to track and trace surgical instruments, sets and individual items. RFID tags are either embedded in or attached to surgical knives, clamps, scissors, etc. the system captures the histories (e.g., records of sharpening, disinfection, etc.) of the tools. Information about past surgical operations are associated with the RFID tags. Must display warning.
- http://www.vernon-carcus.co.uk/products_perioperative.php?cat=76&pid=103
- <http://www.spacecode-rfid.com/> :
- <http://www.mbs.ch/content/view/full/13/125>
- <http://www.mems-id.com/index.htm> Micro Electro-Mechanical Systems
- <http://www.maqtech.com.au/>
- <http://www.keysurgical.com/infoDot/index.cfm>
- http://www.colder.com/asp_main/techspec%5Ctuidc.asp :
- <http://www.krdc.co.jp/>

Coming out with 125Mhz for **Gamma Radiation**
125Mhz
Currently under development - **Disruptive Technology**
13.56Mhz
infodot technology
RFID technology to its subminiature (SMC) couplings
13.56Mhz

Surgical Instrument Tracking Software:

- <http://www.censis.net/tracking/index.htm>
- <http://www.rosebudolutions.com/home.htm>
- <http://www.total-trace.co.uk/uk/home.asp>
- <http://www.aesculapusa.com/index.cfm?9f447e84990841128f8090f333e4003c>
- <http://www.matrxmarking.co.uk/Pages/HowaSystemFits.htm>
- <http://www.tqmedical.com/>

Future Solution:

A electronically charged 3D thermally stable chemical nanomaterial coating that uses the instrument as an antenna and will change color for sterilization surety

- 3D rendering of thermally stable nanomaterial is a chemistry breakthrough. (http://news.com.com/2300-11395_3-6108254-1.html) The ability to cast the nano material into 3D forms will allow it to be used in protective masks and armor, flame-retardant fabric, drug release capsules and regenerating tissue. The application could applied to a the nanowire bar code system currently in use for detecting anthrax (http://news.com.com/Nanowires+built+to+fight+bioterrorism/2100-11393_3-6103410.html?tag=nl).
- Thermal stability, might lend itself to repetitious physical property changes (color) as temperature changes (Liquid Crystal). Combined with an electric charge a simple binary bit structure can record each event

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Privacy-Preserving Indexing:

PPI in Brief Page 1 of 2

PPI is a way to preserve anonymity even if someone is able to circumvent your security measures and get a copy of your data files.

PPI is a lookup index and is best explained by using Google as an example.

With standard indexing techniques that are not interested in anonymity, you would find these exact entries if you type in "Brad Sokol":

- Fast Track Technologies, Ltd.
- The future adaptation of RFID to the healthcare industry
- Brad Sokol
- Brad Sokol Filmography – Yahoo! Movies
- Etc.

The Google index tells you exactly where they got their information from. This is **not** an anonymous database.

If I searched for "Virtual Medical Worlds Magazine," I would find an entry for Brad Sokol. There are a lot of terms that I can use to find entries about Brad Sokol. If I do enough searches, I can piece all the information together and reconstruct the original document that Google used to build its index. That means if I stole a copy of their index, I could reconstruct the original documents if I had enough time.

In the medical environment, this type of index can yield a lot of information to a computer hacker. They can find out the source of the original document, and with enough time, all the information the original document contained.

A PPI index is very similar to the Google index, except it intentionally has erroneous entries. It has to have more than 50% erroneous entries.

If Google used a PPI index, I might get the following results if I searched for Brad Sokol:

Msbe.dll Windows process – What is it?

Fast Track Technologies, Ltd.

The future adaptation of RFID to the healthcare industry

Internet Ray Tracing Competition: March-April 2003

IRTC statistics

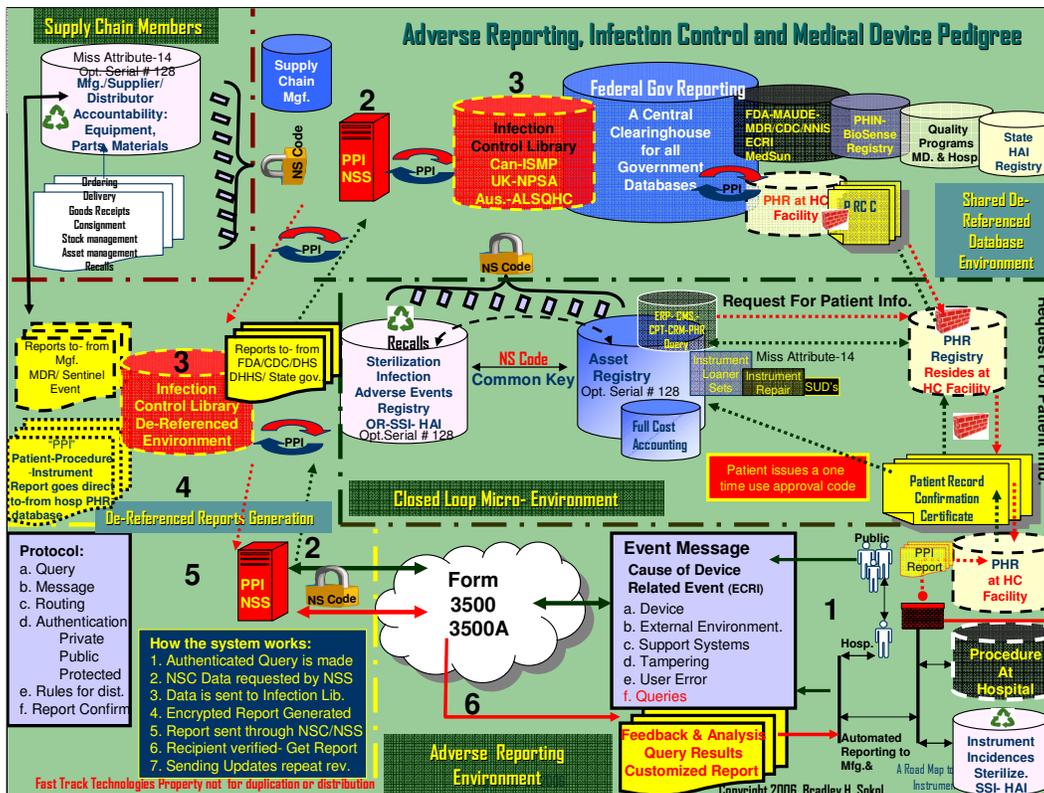
Brad Sokol

Manufacturing Business – Advanced Software Technology

Brad Sokol Filmography – Yahoo! Movies

Etc.

Source:http://www.almaden.ibm.com/software/quest/Publications/papers/vldb03_ppi.pdf



Privacy-Preserving Indexing

PPI in Brief Page 2 of 2

This forces me to perform an extra step – I have to click on each of these links to see if they really have some information about Brad Sokol. Also, if I steal a copy of the index, there is enough false information in it that makes it extremely difficult to reconstruct the original documents.

If you implement PPI in the NSS, the process will look like this:

A manufacturer might submit a report about a defect in a particular device

The NSS would add key information into its index like the manufacturer's name, part number, hospital where the device was used, problem description, etc.

The NSS would include false information about the incident

- Other manufacturer's names

- Other hospitals where the part was used

- References to other database where more information can be found (but not really)

When a person does a query on the manufacturer to find out how many incidents they have had in the last year, the index would have too many because it has used that manufacturer's name to create other false index entries for other manufacturers.

The NSS has to perform a lookup for each entry to see if it's actually valid. That means it might have to query the manufacturer's history database, the hospital's database, etc. for each entry that it found to find if they are actual entries or false entries.

The NSS then returns only the entries that prove to be accurate to the person who performed the query.

The original documents cannot be reconstructed if someone gains access to the PPI index. Anonymity is preserved.

Source: http://www.almaden.ibm.com/software/quest/Publications/papers/vldb03_ppi.pdf

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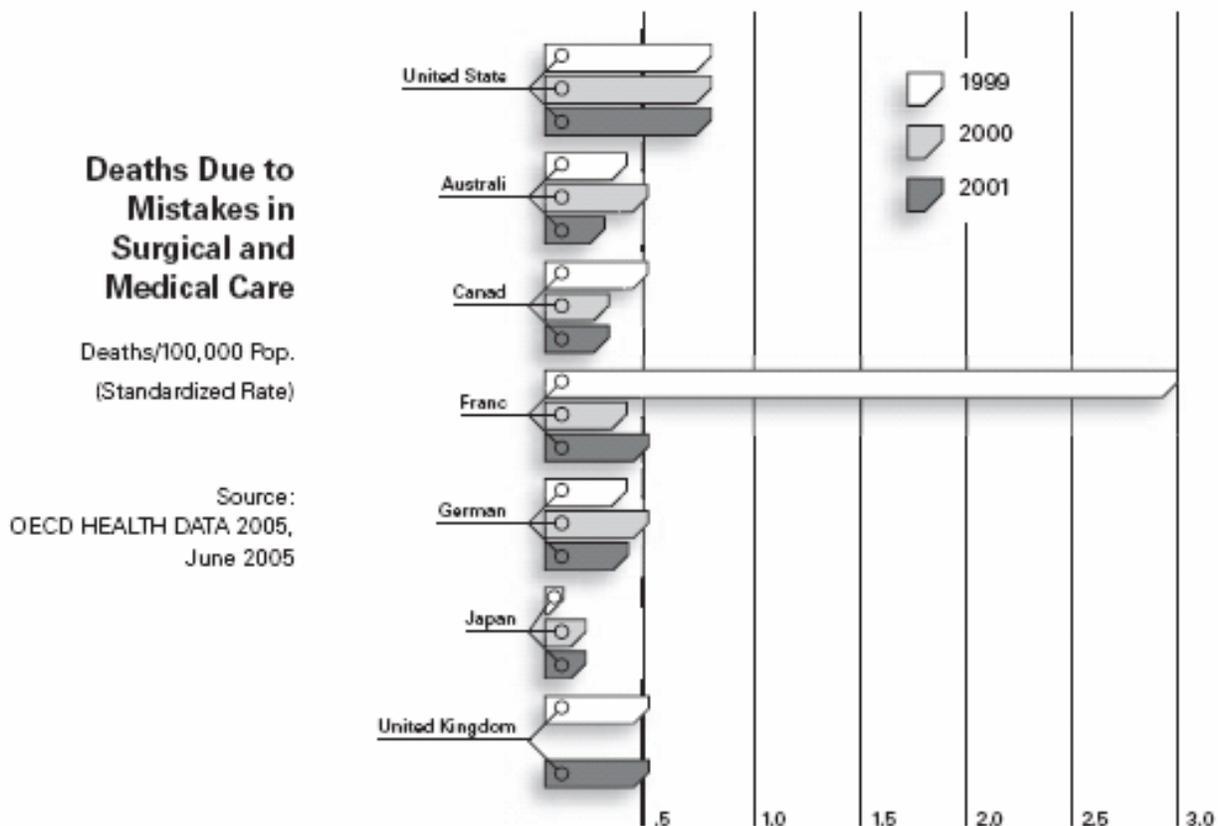
Chain of Transmission - Mortality

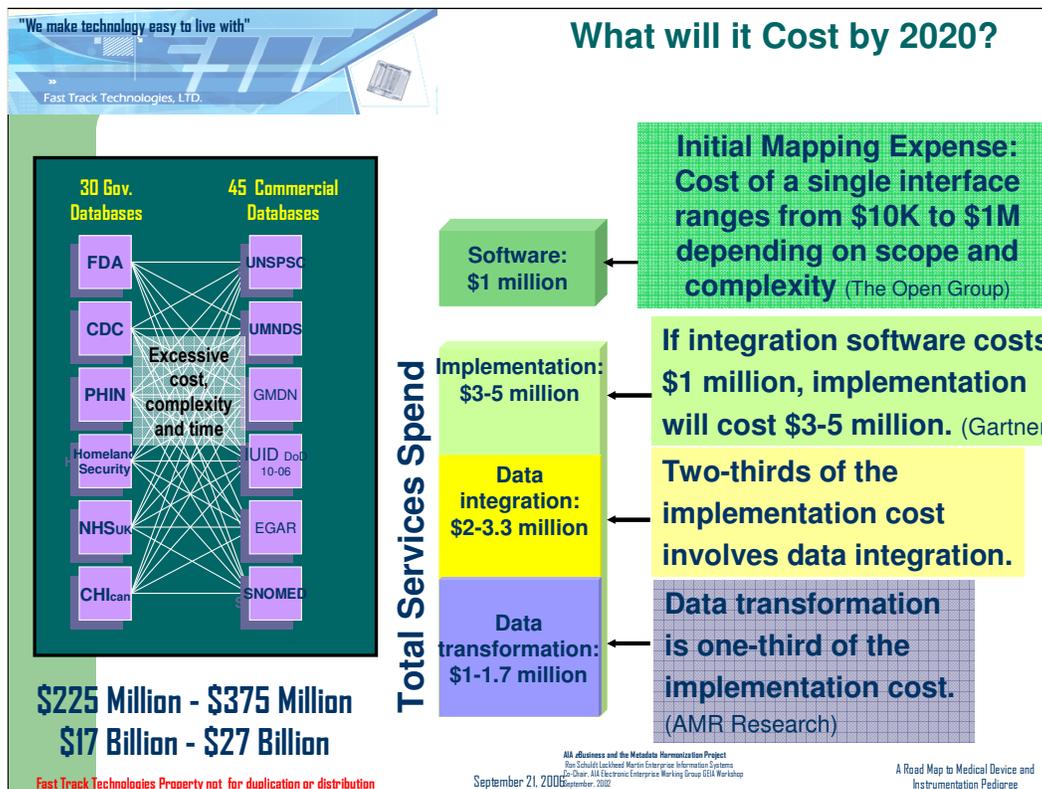
Fast Track Findings concerning Medical Device, Instrument and Supplies mortalities, based on 90 procedural studies performed in hospitals from 1990-2005 :

- **3.4% percent of infection mortalities were directly attributable to MD&I.** The primary cause was the lack of sterilization, cross (chain of transferred) infections, storage, transport and cleaning protocol.
- **An Additional 16.6% of infections were indirectly attributable MD&I mortalities result due to instrument wounds, cross contamination, software malfunctions, surgical cleanliness environment and improper assembly, packaging and poor labeling (quality information) of MD&I**
- **8% of instruments are used more than once a day**
- **26% of instruments are processed within a day"** Sterilization of Medical Devices in France - Current and Future Trends, Business Briefing: Medical device Manufacturing Technology 2002
- **Medical equipment-related 1.3% believed to be underreported by the factor of 10 - 13%:** 2000 annual event statistics 0-2004 <http://www.dhs.gov/ohrt/patients/ohrt.html>
- **The important variables for infection were central venous catheter, mechanical ventilation, drainage and trauma with open fractures.** "Risk factors for nosocomial intensive care infection: a long-term prospective analysis" P. Appelgren, I. Hellström, E. Weitzberg, V. Söderlund, L. Bindslev and U. Ransjö
- **5% -10% percent of in-patients acquiring one or more infections during their hospitalization.** Burke JP. Infection control - a problem for patient safety. *ACM* 2002; 34(8): 651-656

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Since 2003, Ten states have passed legislation mandating the reporting of HAI data, and more than 30 other states have similar legislation pending, with varying reporting requirements, making it impossible to compare or aggregate the reported data.





We have a board of directors that is balanced and a product and pricing committee that is split between hospital and suppliers." He says that GHX operates on a \$35 million cost structure generated by a combination of \$20,000 per hospital integration fees plus an ongoing software maintenance fee depending on the GHX services a hospital uses, along with an annual fee paid by each participating supplier. He says GHX is open to any supplier for unlimited use. http://findarticles.com/p/articles/mi_m0BPC/is_3_27/ai_99121147

1. The parties to each transaction own the data relating to that transaction. The parties are the buyer (e.g., the hospital) and seller (e.g., the manufacturer). If a distributor is legally an agent, then its rights to data are governed by its agreement with the seller, If a distributor is legally the seller, then the manufacturer's rights to data are governed by its agreement with the distributor.
2. The exchange will not disclose transaction specific data to anyone without the consent of the buyer or seller.
3. The Exchange may sell aggregated data. Aggregate data may not identify participants, individuals or particular transactions. Aggregate data will only include data from buyers and sellers who consent.

Curt Werner "[Post-merger Global Healthcare Exchange seeks a balanced market - News](#)". Healthcare Purchasing News. March 2003.

MedSun: Costs about \$20,000 to add a hospital to the system
 Source: (Kerber, *Boston Globe*, 7/14/06).September 19, 2006

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Take Away



1. Linked the significance of Pedigree, sterilization- instrument-procedure-patient.
2. Explained the NSC and it's importance to pedigree and privacy
3. Highlighted the security exchange between the NSS- De-registered Database Environment and Privacy Preserving Index (PPI)
4. Established a case for Medical Tool Pedigree based on reducing 26,000 mortalities annually through automating systems, procedures and workflow
5. Demonstrated how to protected the privacy rights of Individuals and Manufacturers
6. Paralleled the EPC data construct and explained how the 128bit User Memory would be applied throughout a medical device life cycle in Sterilization, Maintenance, Remanufactured, Recall, Rental and Loaner scenarios
7. Established a case to Incorporate Medical Device Pedigree in the Interoperability Healthcare Model
8. Provided resources available today to investigate the implementation of a closed loop Medical Device Pedigree.

Thank You
Brad Sokol; Fast Track Technologies, Ltd.
A Road Map to Medical Device and Instrumentation Pedigree

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Cost of System: Use Case:

Hospitals in England during the last four months experienced more than 110 "major incidents" after the National Health Service went live with parts of its \$23.4 billion IT upgrade, *Computer Weekly* reports. The NHS IT project, which includes an online booking system, electronic prescriptions and an electronic health records system for 50 million patients, aims to connect more than 30,000 physicians to 300 hospitals by 2014, *BBC News* reports. The online booking system already is a year behind schedule, and the EHR system is at least two years behind schedule (*BBC News*, 9/18).

<http://www.ihealthbeat.org/index.cfm?action=dspItem&itemID=125063&changedID=125043>

Total system cost for the USA:

Manufactures: 15,000 x \$100,000 = 15 Billion
 Hospitals 6,000 x 33,000 = 2 Billion
 Government 100 x 5,000,000 = .5 Billion
 Organizations 200 x 2,500,000 = 5 Billion
 Total = \$17 to \$27 Billion Dollars
 Total Reoccurring Costs- 20% of total cost a year.



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On The Shoulders of Giants

- "An Introduction to the Universal Data Element Framework" (UDEF) October 20, 2005 The Open Group UDEF Forum Ron Schuldt, Chair; AFEI (formerly CALS ISG) holds the Intellectual Property Rights to the UDEF- <http://www.afei.org/>
- "Unique Identification Needs and Initiatives" June 27, 2005 Deputy Program Manager for UID Robert Leibrandt; A Guide to the Coalition for Healthcare eStandards Initiatives: www.CHeStandards.org Customer Identification, Product Identification and Product Classification Joe Pleasant (Broad Member) (CIO Premier)
- "Multi-Layer XML Event, Data And Process Model For EPC/RFID", OASIS Open Standards Sydney, Australia October 28, 2005- Ash Parikh, Varun Gupta
- "ePedigree and RFID/EPC" cyclone commerce February 14, 2005, Lars Rajahn
- "Public Health Information Network- BioSense" February 24, 2003 John W. Loonsk, M.D. Associate Director for Informatics Centers for Disease Control and Prevention
- "Privacy-Preserving Indexing of Documents on the Network" Stanford University- *Stanford, CA 94305* Mayank Bawa bawa@db.stanford.edu IBM Almaden Research Center- *San Jose, CA 95120* Roberto J. Bayardo Jr. rbayardo@almaden.ibm.com Rakesh Agrawal, ragrawal@almaden.ibm.com July 8, 2003
- "Research Agenda for the Semantic Grid: A Future e-Science Infrastructure," National e- Science Centre, Edinburgh, UK UKeS-2002-02, D. De Roure, N. R. Jennings, and N. R. Shadbolt December 2001
- "A Patient Safety Network: Proposal from the DHHS Patient Safety Task Force for Stakeholder Consideration" April 20, 2001 Julie Louise Gerberding, MD MPH Division of Healthcare Quality Promotion National Center for Infectious Diseases Centers for Disease Control and Prevention

Other Contending Universal Translators

PUD: <http://www.chestandards.org/pdu/pdumain.htm> Open: Nonprofit- being developed- 24 Members

UDEF: <http://www.udef.com/> Open: Many members from across the DoD and Aeronautics industries -295 Members

PLDS: http://www.oasis-open.org/committees/tc_home.php?wg_abbrev=plds : Open: Nonprofit :controlled by a couple of corporate membership. (In use DoD) 14 members

GHX: <http://home.ghx.com/UsingGHXMain.asp> Commercial: currently in use. 2,200 hospitals- more than 150 supplier divisions: GHX has as Abbott Laboratories, Medtronic, Baxter, Johnson & Johnson and GE Medical Systems. 17 strategic investors.

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September 21, 2006

A Road Map to Medical Device and Instrumentation Pedigree

Bill To Create Disease Detection Network

July 25, 2006

The Senate Health, Education, Labor and Pensions Committee this month approved a bill ([S 3678](#)) that would give HHS two years to build a network to identify disease outbreaks, [Government Health IT](#) reports.

The bill, which was introduced by Sen. Richard Burr (R-N.C.), would shift the responsibility for public health and emergency medical programs from the Department of Homeland Security to HHS. The legislation calls for "a near real-time electronic nationwide public health situational awareness capability" that links existing state systems. Public health departments, federal health agencies, biosurveillance systems, health care providers and laboratories would voluntarily provide data for the system.

The bill also would create a new grants program for states and other entities totaling \$102 million in the next year, [Government Health IT](#) reports. The bill would allocate \$35 million of the \$102 million specifically for biosurveillance (Ferris, [Government Health IT](#), 7/24).

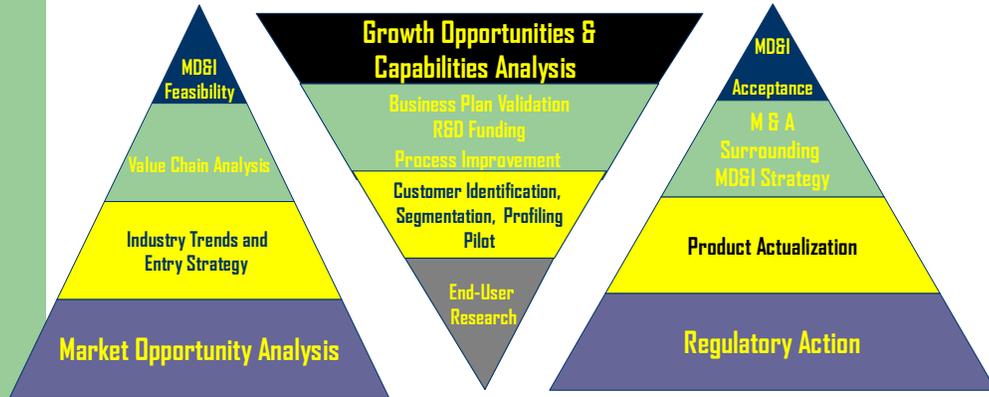
Next Steps:

1. Coordinate premarketing and postmarketing information to ensure full consideration of all available safety data at each stage of review.
2. Supplement existing reporting channels by establishing and supporting institutions to serve as sentinel sites for adverse event reporting. Such sites would produce a higher rate of event reports and more completely analyze each event, further enhancing the value of their reports.
3. Provide cross-agency access to external healthcare databases. This would allow the Agency to more quickly investigate signals generated by spontaneous reports and would be particularly valuable in determining the rate of adverse events.
4. Design, implement, and maintain prospective product use registries (the bulk of support should come from manufacturers).
5. Increase resources to conduct focused epidemiological studies when support of these studies by manufacturers is not feasible.
6. Conduct methodological research in adverse event surveillance.

Adapted from: Position of the Pharmaceutical Research and Manufacturers of America May 12, 2005

Concept to Market

By using both process improvement based on regulatory initiatives, coupled with affordable integration of commercial technology solutions, we will enable and produce, positive results to a manual process. *"Improving the quality of life for those who are touched by healthcare tools"*[©]



Theorize

Analyze

Empirical Proof

Medical Consulting Consortium

Patient Record Entity Relationship Diagram for Future Incorporation into the Model

