

"Rationale for a Unique Device Identifier"

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By using affordable commercial technology solutions combined with regulatory initiatives, we improve health provider's processes, increase patient safety and quality of care.

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- **Why we need a UDI**

- Preventing **13,000-26,000 mortalities** in the US a year, from direct and indirect medical device procedure/ process infections
- **Saving \$3.1 Billion** a year from direct and indirect medical device procedure/ process infections
- Develop a comprehensive **interoperability healthcare model** to include medical non-electrical instruments and supplies

- **Factors to Consider for a UDI System**

- **UDI's Drivers**

- **The Impact of a Universal Device Identifier**

- **Concluding Remarks**

- **Ability to incorporate the UDI system into the Interoperability healthcare model**
- **Address unique life cycle events experienced by a medical device:**
 - **Reprocessing of medical devices and the associated regulations (FDC 502.u, SUD's)**
 - **Distributor re-labeling**
 - **Rentals**
 - **Loaners**
 - **Sterilization cycles**
 - **Maintenance cycles**
 - **FDA MDR/MHR and reporting**
 - **Adverse Event Reporting**
 - **State HAI Reporting**

- **Creating a De- Referenced Database environment where all authorized queries have Confidentiality, Integrity, Authentication and Anonymity”**
- **Patient privacy is controlled by the Patient so that they personally distribute and allow limited informational access by the inquiring party to their Patient health record.**
- **Focus on infection control: Designed a model to increase our abilities to better detect the chain of transmission infections, by integrating the UDI, procedure and patient record systems.**
- **Getting past the vested economic and political bias of the current players.**

- Device maintenance and increase regulatory compliance reporting, – in cases where infections have been passed from patient to patient due to improper device maintenance (Chain of Transmission)
- Reduce theft and counterfeiting of medical devices, Adverse Events warnings/notification
- Enable a process to track the reprocessing, recalls, rentals, loaning of medical devices and Reduce Counterfeit Instruments

- Increase supply chain asset visibility resulting in, increased productivity, administrative efficiencies, billing accuracy and reduction in Liabilities
- Matching patient data records to diagnosis, treatment and device to patient schedule/procedure and infection cause.
- Reduction of hospital associated infections and length of stay, reducing mortalities through ensuring sterilization and proper device usage on the correct patient.

The Impact of a Universal Device Identifier

Issue	Solution	Result
<p>Lack of informatic tools and interoperability standards to connect nomenclature to procedure, Patient records, Infection Control.</p> <p>What patients were treated with which devices?</p>	<p>Track process order events "The 7 Device L's":</p> <ol style="list-style-type: none"> 1. last manufacturer 2. last maintenance 3. last sterilization 4. last location 5. last user 6. last procedure 7. last patient. 	<p>13,000-26,000 mortalities could be prevent in the US a year by developing a UDI pedigree model for medical tools in the healthcare Micro and Macro supply chain: Saving \$5 Billion a year</p>
<p>11 competing nomenclature systems for the naming of medical devices</p>	<p>A "Universal Translator" (Nomenclature Sequencer Code)</p>	<p>Integrated global semantics into a unified interoperable relational standard</p>
<p>Lack of System "Confidentiality, Integrity and Authentication."</p>	<p>Privacy Preserving Index (PPI): Erroneous Data Generator and Filter</p>	<p>A secure relational database (NSS) that directs queries and information through the PPI creating a de-registered database environment for both Patient and Manufacturer</p>

The Impact of a Universal Device Identifier

Issue	Solution	Result
<p>How to account for maintenance, sterilization verification, reprocessing, loaning and rentals of Medical tools.</p>	<p>Placing additional data fields on an Auto-ID label</p>	<p>Third Party Liability Shift Labeling compliance Increased financial and compliance reporting efficiencies</p>
<p>Patient "Confidentiality, Integrity and Authentication."</p>	<p>Patient Controls release of personal information Patient Record Confirmation Certificate</p>	<p>Several security check points culminating in the patient issuing a one time access code to the inquiring party</p>
<p>Inconsistent reporting of Adverse events</p>	<p>A rules based semi-automated mandatory reporting system of adverse medical device related events</p>	<p>Combined reach and techniques of MedSun and MAUDE with the robust event reporting features of ECRI Alerts Tracker. i.e. CDC-National Healthcare Safety Network</p>
<p>There are no plans to include Medical Instruments or Supplies In today's Global Healthcare Interoperability Models</p>	<p>UDI</p>	<p>A Complete Healthcare Interoperability model and all the gains realized: financial, efficiency, safety and quality</p>

- Failure to incorporate the 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.
- **If we wait until UDI/Infection Control yields an immediate ROI or until we reach a global political compromise it may be too late.**
- **Don't wait for a catastrophic disease outbreak to implement UDI.**

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Thank You!

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A Road Map to
Medical Device and Instrumentation Pedigree