



The National Alliance for  
Health Information Technology

One North Franklin Street  
Chicago, Illinois 60606  
312 422 2181 phone  
312 422 2190 fax  
www.nahit.org

November 9, 2006

Attn:  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: FDA Request for Comments, Unique Device Identification:  
[Docket No. 2006N-0292]

The National Alliance for Health Information Technology thanks the Food and Drug Administration for the opportunity to respond to its request for comments concerning a system of unique identifiers for medical devices. The Alliance is a diverse partnership of leaders from all healthcare sectors working to advance the adoption of clinical information technology systems to achieve measurable improvements in patient safety, quality of care and operating performance. The Alliance is unique in its ability as a convener to bring together teams of senior executives across and outside of healthcare to overcome barriers and accumulate a critical network of technical and intellectual knowledge and leadership, enabling them to optimize technology to realize the highest level of patient care and enhanced financial performance.

Collaborating with healthcare and government leaders, the Alliance is working to shape the policy environment and accelerate the implementation of world-class, standards-based information technology aimed at creating the most effective, safe, unified and inclusive health system possible. The Alliance has taken a leadership role in several key areas: advocating for the creation of the National Coordinator for Health Information Technology office, creating the Certification Commission for Healthcare Information Technology, recommending the adoption of barcoding and electronic health record standards, actively promoting standards use through the Alliance Standards Directory, and developing an industry-endorsed interoperability definition.

The Alliance comprises over 100 member organizations from all industry sectors: providers (medical groups, care providers), payors/health plans, supply chain,

information technology suppliers, employers/purchasers, and other relevant non-healthcare organizations.

### **General comments**

The Alliance generally agrees with the vision expressed in the Request for Comments by the FDA regarding a unique identifier for medical devices, but membership differs on its potential influence on patient safety in addition to supply chain efficiency. Membership also differs on whether or not the minimum data set includes a serial number.

## **Developing a System of Unique Device Identifiers Questions 1-8**

All processes related to device identification throughout the supply chain must be created consistently in order to encourage user adoption. Likewise, there must be significant adoption by users in order to see the benefits of implementing such a system including reducing medical errors, facilitating device recalls, and improving adverse event reporting for all devices.

The Alliance believes all devices, where practical to do so, should carry a Unique Device Identifier (UDI). How this practicality is determined will depend on the type of device, whether or not a serial number is required, and whether or not it is physically possible to display a UDI on the device. In the event that it is physically impossible to display a UDI on a device, the identifier should still be on the packaging that contains the device. See Appendix A for more detailed demonstration of the complexities affecting this decision.

Where a device ID is warranted, all levels of packaging from individual unit to pallet should be identified in order to further optimize the supply chain, and is especially useful for recalls and tracking.

### **Human Readable IDs**

Where practical, the Alliance recommends the UDI be both human and machine readable. Human readable UDIs will provide an opportunity for slower adopters of automated technologies to, in the interim, take advantage of the benefits associated with having an identifier either printed or engraved on the device. Human readable identifiers may be impractical on devices that are too small to carry a visible identifier. In such cases, the ID will be machine readable only.

### **Machine Readable IDs**

In order for machines to automatically read a UDI, the information must be represented in a format that is recognizable to the reading machine. Data

“carriers” of the information fall into two categories: bar codes and transmitting identification tags. The latter category includes Radio Frequency Identification (RFID) tags or tags with similar signal transmission capabilities; collectively, these types of tags are known as Real Time Location Systems (RTLS). Bar codes are read by a device that requires line of sight access to the code being read, usually with the aid of human intervention. RTLS tags can transmit their information without line-of-sight proximity via radio, ultrasound or infra-red signals to a receiver that interprets the code and automatically enters it into the system. RTLS tags can be either active (they have batteries and transmit their data out to the receiver) or passive (the tag is not powered, and is activated only by a “request” signal device, which then listens for the response from the tag).

Use of these technologies is growing in healthcare; however, there is no healthcare-wide system of identifying products. Consequently, hospitals, distributors and other organizations that want to take advantage of the benefits of unique identifiers must currently create their own identification schemes. This constrains the patient safety benefit, limiting it just to the organization. An industry-wide standard for device identification, on the other hand, will enable the system-wide benefits of auto-ID technologies to be realized. As these devices continue to shrink in size and hold more information, they will continue to generate interest for healthcare uses.

The principal conclusions that can be drawn at this point are that there are several carrier technologies that can be used. For example, bar code and RTLS technologies are highly appropriate for items and devices that require no other connectivity than that required for identifying the device.

The Alliance recommends that, where possible, existing methods of creating, issuing and maintaining UDIs be adopted by medical device manufacturers. There are globally accepted standards for doing this, and the FDA should mandate that the manufacturers of medical devices under its purview adopt one of these existing standards for creating and representing a UDI. For example, the GS1 system is widely used by many industries, and allows the use of a product identifier, global location number (GLN) as well as other identifying attributes that streamline the supply chain. Computerized devices that communicate over networks or with other devices are each issued a globally unique identifier by IEEE, and this format could be adopted for healthcare purposes if appropriate.

It is important that we first adopt and develop the UDI numbering system before we move into the adoption and selection of standard data carriers for the UDIs. Without a UDI numbering system that is adopted globally, we will not successfully use and adopt universal data carriers across the healthcare supply chain. As is the case in other industries, we may find that each class of UDI may use a variety of carriers due to the size, expense, use and distribution needs of the product.

## **Implementing Unique Device Identifiers Questions 9-12**

### **The UDI**

There is consensus across the Alliance membership that there is value to be found in being able to identify medical devices. There is also agreement that the minimum data set must include a way to uniquely identify the device manufacturer, the product type and the lot. There is no consensus regarding whether or not serialization is required. The majority contends that serialization should depend on the degree of risk to patients, and is therefore tied to the class of device: If there is risk, serialization should be required. Others contend that serialization is required of all devices in addition to the manufacturer number and lot number. It should be noted that devices that communicate over the Internet or practically any hospital network (wired or wireless), must use an IEEE EUI-64, which includes only a 24-bit vendor identifier (assigned by the IEEE) and a 40-bit serial number (assigned by the vendor). In this case, because the identifier is known, additional information about the device can be derived from its record held in the Product Data Utility, or PDU.

### **Product Data Utility**

A PDU is an essential component of a functioning UDI system. It is a repository of product information maintained and updated by the manufacturers, and can link basic information about a device to a database containing more detailed information such as software version, date of manufacture, etc.

The PDU can facilitate use of different vendor IDs via cross-mapping. Currently, manufacturer IDs are not uniform across systems because they are issued by different entities such as GS1, IEEE, etc., and use different sequencing to issue their numbers. This however is no longer a problem when using the PDU as described above.

The table below illustrates how the various levels of information can be associated with a device depending upon the technology employed.

<b>Minimum Data Set</b>		
<b>Human Readable</b>	<b>Machine readable, (Barcodes or other Auto-ID)</b>	<b>PDU</b>
<ul style="list-style-type: none"> <li>• Vendor Number</li> <li>• Product Model</li> <li>• Serial Number*</li> </ul>	<ul style="list-style-type: none"> <li>• Vendor Number</li> <li>• Serial Number*</li> <li>• Product Model</li> <li>• Expiration Date</li> <li>• Lot Number</li> </ul>	Any number of attributes desired: e.g. <ul style="list-style-type: none"> <li>• place of manufacture</li> <li>• date of manufacture</li> <li>• size and / or color</li> <li>• software version etc.</li> </ul>
*Where determined necessary		

**Product Classification**

A standardized product classification system holds value for the proper and consistent functioning of a PDU. As an example, the United Nations Standard Products and Services Code (UNSPSC) is a hierarchical scheme for classifying products and services; the Global Medical Device Nomenclature (GMDN) is a collection of terms used to describe medical devices. The FDA should look at such systems and determine their usefulness relative to the creation of a UDI system.

**UDI Benefits and Costs  
Questions 13-20**

The Alliance believes there are significant benefits to implementing a UDI system for medical devices, and the benefits can be divided into two major categories: 1) patient safety and 2) supply chain efficiency.

**Patient Safety**

It is at the point of use, in a healthcare setting, that the benefit of a uniquely identified device shifts from one of supply chain efficiency to one of patient safety. Most Alliance members agreed that the adoption of a UDI system will also affect real-time delivery of clinical care, allowing the association of patient, caregiver, device and episode of care. Each device can be tracked all the way to its point of use. For example, if infusion pumps are uniquely identified and labeled with a machine readable ID, the administering nurse’s ID tag could be scanned, along with the pump, the drug being administered, and the patient’s ID tag. In the case of an adverse dosage event, this information will enable tracking

back to determine if it was due to human error or machine malfunction. We did not have complete consensus on the patient safety benefit.

The ability to uniquely identify medical devices will also improve the efficiency of recalls and updates, as well as eliminate the problem of using devices that may have been previously recalled. The Alliance further recommends that the FDA consider any data related to the improved efficiency of recalls since the implementation of bar codes on pharmaceuticals.

### **Supply Chain Efficiency**

The ability to track individual devices as they move through the supply chain will eliminate many of the current inefficiencies borne by manufacturers, distributors and hospitals. Ten-year-old figures of potential savings on the supply side of the equation estimate at least \$11 Billion is wasted due to the inability of these stakeholders to positively identify products as they move from point of manufacture to the point of use in a hospital.

When combined with the patient safety benefits, unique device identifiers enable a much broader infrastructure that in turn enables a safety-oriented healthcare system.

There is a benefit that crosses both the patient safety and supply chain efficiency section related to device tracking. Once devices are in use within an organization, they become difficult to track/find. Although RFID tracking will assist in knowing WHERE a device may be located, a UDI will more clearly allow us to know WHAT the device is.

## Appendix A

This table shows some of the various factors involved in determining the method of representing the UDI.

Device Category	Connectivity	Identifier Options	Examples
<b>None</b>	None	On packaging	Ear and throat swabs
<b>Lot Code</b>	None	Auto-ID	Glucose test strips
<b>Serialized - Disposable</b>	None	Auto-ID	Multiple reagent test cassettes
<b>Serialized - Implanted</b>	None	X-ray detectable pattern, bar code?	Hip prosthesis
	Point-to-point	Protocol over RF transport	Cardiac pacemaker/defibrillator
<b>Serialized - Device</b>	None	Auto-ID	NIBP pressure manometer
	Point-to-point	Protocol (EUI-64) plus Auto-ID	Glucose meter
	Networked	Protocol (EUI-64) plus Auto-ID	Bedside patient monitor
<b>Serialized - Large System</b>	Networked	Protocol (HL7 or DICOM OID; EUI-64)	DICOM image archive system

The principal categories in Table 1 include:

- (1) '**None**', for devices and items that do not require or cannot accommodate an identifier;
- (2) '**Lot Code**', for devices and items that are identified by lot code only and are not individually serialized; and
- (3) '**Serialized**', for devices and items that require individual serialization.

There are several distinct groups within the 'Serialized' category:

- (3A) '**Serialized - Disposable**', for disposable devices and items;
- (3B) '**Serialized - Implanted**', for implanted devices and items;
- (3C) '**Serialized - Device**', for non-implanted devices and systems; and
- (3D) '**Serialized - Large System**', for 'large systems', typically having one or more network interfaces.

Each of these groups has several 'preferred' methods of uniquely identifying an item, device or system, using one or more of the following technologies:

**Bar code**, typically using standards administered by GS1;

**RFID**, typically using standards administered by EPC;

**Point-to-point** communication, typically using proprietary protocols and non-standard identifiers;

**Point-to-point** and **network** communication using IEEE 11073, using the **IEEE 'EUI-64'** identifier;

**Network** communication, typically using Internet, IETF and IEEE standards, using the **IEEE 'EUI-64'** identifier;

**Network** communication, using **HL7 or DICOM 'OID's** (Object Identifiers).

## Appendix B

### FDA Questions

#### Developing a System of Unique Device Identifiers

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?
2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?
3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?
4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?
5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.
6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?
7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?
8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

#### Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?
10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?
11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser etched) for certain devices?
12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what

type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?

#### UDI Benefits and Costs

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify?
14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support benefits you identify.
15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?
16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?
17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?
18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside barcoding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?
19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?
20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?