

**Reference:** FDA [Docket No. 2006N-0292], UDI, Request for Comments

### **Executive Summary**

Since the IOM report, "To Errs Is Human: Building A Safer Health System," which pointed out barcode as an effective remedy for medication errors, there have been many activities in hospitals to improve patient care and safety using automatic identification (AutoID) technologies, which include linear barcode, 2D barcode and various forms of RFID (radio frequency identification). It has been assumed that a proper implementation of these technologies will improve patient care and patient safety by creating a unique identification of each item and each relationship among items for a given space and time. There have been several very successful independent AutoID implementations to reduce medication errors by several hospital groups. Also, there are several successful asset management projects using active RFID.

Beyond the hospitals, there have been several major efforts to implementation of AutoID technologies to improve operational issues, in several different areas. On the fast moving good side, a major push by companies like Gillette and Wal-Mart has empowered EPCglobal to create a numbering scheme and ancillary support infrastructure, which may be supported by required membership fee related to the value of yearly commercial transactions. On the military side, The U.S. Department of Defense (DoD) has a massive on-going effort known as item unique identification (IUID) since 2002. Unlike the fast moving good side, DoD does not require a yearly membership fee for a supplier to work with DoD, by managing its own IUID registry and materials for implementation guidance and training, communication tools and business rules as well as actively supporting new ISO standards. On the pharmaceutical side, there have been few work-in-progress AutoID implementations by few pharmaceutical companies using a scheme proposed by EPCglobal, which may require a mandatory membership fee.

The requirements for patient safety are fundamentally different from the requirements for managing fast moving goods like water bottles or boxes of cereals by Wal-Mart or automobile tires by tire manufactures. If we are to design and implement a system to improve patient safety, we need to design a system, which has the capability of preventing every type of errors we know without creating unwanted side affects. Also, the system must be cost effective without creating undue burdens on manufactures such that every manufactures should be willing to implement without a hesitation. I believe it is feasible to design and implement such a cost effective system for medical devices, since most components for the system exist already.

In closing, if I may, I would like to recommend:

- A) FDA to create and manage its own registry numbers. The cost of obtaining a registry number must not be a barrier for any institution.
- B) FDA to focus on the needs of end users at hospitals. If the information is not used by the patient care providers at hospitals, the good intention of FDA will have minimal impact in improving patient safety.
- C) FDA to focus more on information content, and less on information carrier. As information carrier technology evolves, we should be allowed to take advantages of new cost effective technologies.

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***Responses to questions asked by FDA in its Request for Comment.***

***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?**

The UDI (Unique Device Identification) system must be developed so that it is able to improve patient safety as well as supply chain processes and related operations. However, the patient safety must not be compromised to improve business processes.

Since technology for identification, marking, tracking, and management of devices at the item level is expected to evolve continuously, the current discussion should be focused more on information content supporting clinical needs rather than information carrier technologies.

UDI must be able to support the pedigree of every device and life-cycle management processes as well as supply chain related issues like mergers, acquisitions and divestitures of manufactures.

The attributes for UDI should contain two types of information:

- Identification information leading to a globally unique identification
- Descriptive information, essential for clinical applications

By separating the identification from the description, a flexible system can be built to support multiple types of devices.

**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?**

If the purpose of UDI is to improve patient safety within a reasonable period of time, FDA must play an active role in the development and implementation. FDA should play the role to bring order and utility to the medical/surgical commodity. The basic system implementation related to patient safety should be mandatory. However, there could be optional and/or voluntary components.

**3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?**

There are many potential incentives for manufactures as well as healthcare providers: ability to recall items quickly, improving supply chain issues, reducing medical errors.

**4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?**

Depending on how UDI is implemented, there can be many barriers like increasing cost without any benefits to manufactures, and UDI information not being used by hospitals due to lack of support infrastructure,.

The UDI system must be cost effective and have a reasonable return-on-investment (ROI) for manufactures and end users like hospitals.

**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.**

We have tested several technologies to understand the needs of hospitals. We have used active RFID, linear barcode and 2D barcode to manage assets as well as to monitor movements of patients and staff.

**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?**

UDI should be designed for all devices, regardless of how they are used, even though there are devices which would be difficult to manage. Without an ability to trace and track, we would not be able to improve patient care effectively.

**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?**

UDI should be designed to manage each item being used. However, it is possible, for certain products, the unit of issue (like box of tissues) may be more practical, due technology being deployed as well as manufacturing processes.

**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)?**

We have worked with several institutions to understand how new technologies will impact hospital operations, because we have not seen an acceptable turn-key solution. Our experiences are focused on linear barcode, active RFID and 2D barcode.

### ***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?**

I believe there are different requirements for different devices. What we need to know about a box of tissues is very different from what we need to know about neurosurgical implants.

**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?**

All UDI related information should be provided by the manufacturer and the manufacturer should be held accountable for data accuracy. The FDA should maintain the database of minimum data set. The larger database containing additional data could be handled by industry groups.

Due to privacy and commercial competitive issues, availability of UDI data beyond FDA should be considered in the context of a need-to-know and right-to-know.

**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?**

UDI must support both human readable and machine readable information. UDI should be on as many devices as practical.

**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 should be designed to support technologies like 2D barcode, since 2D barcode may be the most cost effective technology to store all UDI information at this time. Since most new barcode readers can read all types of symbology including various linear barcodes and 2D barcodes, FDA should not favor one symbology over others. There should not be compatibility issues any longer with new readers.

### ***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.**

The main issue with a device recall is an ability to quickly identify, locate, and remove the recalled item from use. Without UDI, the ability cannot be created.

UDI is the fundamental building block in reducing medical errors related to medical devices, by providing visibility of items.

**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 these cost estimates.**

I believe DoD IUID office should have better data than anyone else. We are in a process of collecting information from our system based on active RFID, linear barcode, and 2D barcode.

**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?**

As indicated to question 14, we are in a process of collecting information from our implementation.

**16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?**

Without a clear vision of FDA, it could be a very slow process, since end users like hospitals are, in general, may not have enough resources to implement new technology quickly.

**17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?**

The main obstacle is organizational resistance to change.

**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 bar coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?**

Due to lack of understanding about the impact of UDI to patient safety, the level of interests for UDI implementation is low, at this time.

**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?**

Some of infrastructure items required for UDI are: 2D barcode readers to read UDI, inventory database for devices, integrated hospital information system, enterprise-wide resource management system,...

**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?**

A recall based on UDI would be very helpful for every class of devices, assuming the facility has the infrastructure to manage the information.