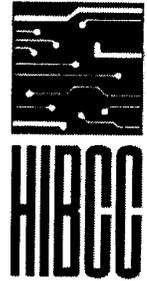


HEALTH INDUSTRY BUSINESS
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Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: HIBCC Comments on Unique Device Identification for Medical Devices
(Docket no. 2006N-0292)**

In response to the Food and Drug Administration's (FDA) request for comments on the benefits and feasibility of implementing a Unique Device Identification System (UDI) for medical devices, the Health Industry Business Communications Council (HIBCC) has prepared the following review.

HIBCC recognizes the FDA for its leadership in efforts to address the need for automated identification (auto-ID) technologies in support of efficiency and safety in the healthcare marketplace. As the industry's primary ANSI-accredited Standards Development Organization (SDO) for auto-ID applications, HIBCC represents the interests of a large constituency of medical device manufacturers and distributors.

HIBCC has provided comments to questions that it considers within its purview; they are presented in the order they appear in the FDA's document.

DEVELOPING A SYSTEM OF UNIQUE DEVICE IDENTIFIERS

Question 1:

How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

HIBCC would encourage the FDA to recommend existing standards for product identification, and to develop specific guidelines for the use of these existing standards for medical devices.

HIBCC would encourage the FDA to adopt American National Standard (ANS) MH10. This standard has also been endorsed by ISO, produced as ISO/IEC 15418. It supports the use of the ANS/HIBC or GTIN, the data standards specified in the FDA's 2004 Rule on Bar Coding of Human Drug Products.

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ANS MH10 includes a vast range of data identifiers to be used in Automatic Data Capture applications. By adopting this standard, the data structure included in the UDI is consistent with existing standards, and compatible with existing systems and technologies, and existing coding practices of manufactures of medical devices. For example, it is estimated that some 90% of implantable devices distributed today are coded with an existing unique identifier based on existing standards. These products are coded with either ANS/HIBC, or GTIN. It should also be noted that the US Department of Defense has issued a specification for the Unique Identification of Items (UII). This specification refers to ANS MH10 for the data structure.

ANS MH10 includes a comprehensive list of Data Identifiers (DI's) to identify items. By way of example, some DI's included in ANS MH10 include:

Data Identifier	Description
25P	Globally unique part number
Q	Quantity
S	Serial Number
T	Lot and Batch Number
14D	Expiration Date (YYYYMMDD)
16D	Production Date (YYYYMMDD)

ANS MH10 is also the umbrella standard under which both the HIBC standard and GTIN (GS1) are recognized. Under ANS MH10, the "+" character which characterizes a HIBC formatted identifier is a valid DI.

HIBCC would recommend that the FDA issue guidelines to medical devices companies on the format of the UDI. We believe that this should vary depending on the type of medical device.

For example, for consumable products such as dressings and gloves, the UDI should consist of a product identifier, and Lot/Batch number. For active implantable devices, however, serialization is important, and therefore the UDI should consist of the product identifier and the serial number for the product. These data formats can be accommodated by the existing ANS/HIBC, GS1 and ANS MH10 standards.

Question 2:

What should be the role, if any, of FDA in the development and implementation of a system for the use of UDI's for medical devices? Should a system be voluntary or mandatory?

The FDA should be responsible for establishing the guidelines and business rules for the implementation of existing standards. These guidelines should designate the format of the UDI (using existing standards) applicable to the different types of medical devices. The type of UDI format should be based on the classification of a medical device, and therefore the risk associated with it.

HIBCC recommends that the UDI should be mandatory. Given the many different technologies that are available for the carrying of the UDI, we recommend that the FDA develops comprehensive guidelines for suppliers to implement. There will be instances where certain technologies will not be viable or practical. For example, barcodes cannot be successfully applied to certain types of products (surgical instrument and other metal parts). 2-D symbologies, however, can be etched onto metal surfaces. Furthermore, there may be instances where none of the available technologies can be applied to the

medical device. This may be the case for screws, plates and other such devices that are used for treating trauma patients. However, at the minimum, all products should be identified by a standard UDI.

Question 3:

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

A UDI system based upon current international standards can provide numerous efficiency and safety benefits throughout the supply chain, including:

For Manufacturers:

- Clear direction and guidance on requirements for product identification;
- Potential to reduce information technology expenditure;
- Potential to improve efficiency, through automation of business processes;
- Consistency;
- Improved supply chain management (from manufacturing through to end user);
- Improved product traceability.

For Healthcare Providers:

- Ability to analyze medical devices expenditure across different jurisdictions, since all expenditure can be linked to the UDI;
- Improved patient safety, through improved product traceability;
- Improved efficiency through the introduction of automation in business processes;
- Potential for reduced cost in Information Technology.

For Software Vendors:

- Clear direction in the design of databases and systems for automatic data capture;
- Standard specifications, meaning consistency across different vendors' systems.

Question 4:

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

There are no significant technical or practical barriers, so long as the FDA supports existing internationally recognized standards.

There are logistical barriers in educating and training small to medium sized manufacturers to implement and conform to the standards. This can be overcome by implementing existing standards, and using the standards organizations (e.g. HIBCC) to educate and assist manufacturers in their implementations.

For companies that are not currently using existing standards (usually small to medium enterprises), there are potential implementation costs. These can be minimized through appropriate guidance. The implementation of existing recognized standards will also mean that the implementation costs overall are kept to a minimum.

Question 6:

Should unique device identifiers be considered for all devices?

HIBCC recommends that all devices are identified with a UDI based on existing standards. However, we recommend that the data elements included in the UDI vary with the class of device. For example, the UDI for active implantable devices should consist of the product identifier, followed by the serial number. The rules for the UDI format for each class of devices should be established by the FDA.

Question 7:

At what level of packaging should UDI's be considered? Should UDI's be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device?

All levels of packaging, including the base unit should be identified with a UDI based on existing standards. Each level of packaging should be uniquely identified. However, the use of an auto-ID technology (e.g. barcode or RFID), should only be applied at the packaging levels where it is practical and feasible to do so, and where there is a distinct benefit.

IMPLEMENTING UNIQUE DEVICE IDENTIFIERS

Question 9:

What is the minimum dataset that should be associated with a unique device identifier? Would this minimum dataset 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?

HIBCC believes that the minimum data set should be determined by the specific application. However, there will also likely be a "common" data set that is applicable across many applications. It is also important to differentiate "static" product data, with "dynamic" data.

Static data includes information that describes the attributes of a product. These attributes generally remain static and are not impacted by day-to-day operations.

Dynamic data is that which is added following a specific transaction. For example, lot number is a dynamic data field, since it will be added to a batch of manufactured like products, and will change with every batch manufactured. In transactions, the lot number is added to the patient record when the product is used. Hence, this data is dynamic.

Furthermore, there will be local and country specific requirements. Medical devices is an international business, and this needs to be taken into consideration in any data model design.

The "common" data set that describes the basic attributes of a medical device includes:

- Unique Product Identifier. This is not necessarily the UDI, since the UDI may also include the serial number or lot/batch number of the product;
- Brand name;
- Product description (including packaging level);
- Units of Measure (to a standard UOM dictionary such as ANSI X.12);
- Quantity (of contents in the package);
- Manufacturers part number;
- Supplier name and details;
- Size;
- Material;
- FDA Registration Number;
- Product classification (e.g. GMDN or ECRI-UMDNS);
- Country of Manufacture;
- Sterility information (including method used to sterilize product);
- Special packaging and transportation requirements;
- Instructions or specific data sheets relating to the device;
- Minimum and maximum temperature storage and transportation.

Minimum data requirements for dynamic data elements pertaining to medical devices are more difficult to define, and are subject to the specific application. It is our view that the data model needs to be defined for each process that is intended for the use of medical devices.

For example, the data elements that are required for successfully tracking medical devices (for example implants) include:

- Serial number or lot number for the product used. This could be the UDI;
- Expiry date (expiry date for implants generally refers to the sterility of the product);
- Patient details;
- Suppliers in distribution chain (wholesaler – distributor etc.);
- Healthcare provider;
- Location within healthcare provider implanting the product – e.g. Specific Cardiac Catheter Lab or operating room;
- Medical clinician(s) responsible for surgery.

Question 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?

HIBCC believes that the most practical means of obtaining and maintaining the minimum dataset is by obligating the manufacturers of medical devices to maintain the data on their information management systems. The FDA should define and specify the minimum data set that the manufacturer is required to maintain. The minimum data set should be made available to the trading partners of the manufacturers, by the manufacturers.

There are some proponents arguing for the development and implementation of central databases to host the UDI and product attribute information. These same proponents argue that the databases are available to manufacturers and healthcare providers over the Internet. For example, the EPC, Object Naming Service (ONS) is such a proposal.

It is HIBCC's view that the FDA should be careful when considering such proposals for their practical merit. By definition, the UDI is a dynamic data identifier, since it identifies not only like products, but specific products down to their manufactured Lot/Batch, or unique serial number. Hosting a central database would require that manufacturers tightly integrate their manufacturing processes and information technology systems to these databases, so that as products are manufactured, the product information (including Lot/Batch or Serial) is appropriately uploaded. In our opinion this is not feasible or practical, and would result in:

- Errors associated with disconnected systems within the manufacturing environment. The consequences of these errors could result in patient safety concerns;
- Expensive investment in information technology by manufacturers of medical devices, and by providers. This will likely increase the cost of medical devices in the market, not reduce;
- Very large databases, since the database is hosting not only basic "like" product attributes, but all manufactured volumes where products are uniquely identified by their Lot/Batch or Serial number;
- Compliance issues for many manufacturers, particularly small to medium enterprises.

It is more practical and feasible that manufacturers provide the product identifier component of the UDI, and associated product attributes, to their trading partners. This is the static data that does not change frequently over time, and where changes made can be easily managed. This is in many ways equivalent to an electronic product catalogue. The auto-id systems implemented within a provider organization would scan the barcode, 2-D symbol or RFID tag, and identify the product from a look-up table resident on the databases within the software application. The Lot/Batch number or serial number, would be populated to the specific databases in the providers application directly from the barcode, 2-D symbol or RFID. This approach is currently used by many applications in healthcare and other industries, and is most likely to succeed.

Question 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?

The UDI should be human readable, but the encoding in an automatic technology should only be mandated for devices where it is practical and beneficial. The requirement for the UDI to be etched on certain devices should only be considered for surgical instruments and other devices that are reused, and that therefore require constant tracking from sterilization processes (CSSD) through to patient use.

Question 12:

Should a UDI be based on the use of a specific technology or be non-specific? Please explain your response. If a barcode is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the barcode be "compatible" with those used for the drug barcode rule? If yes, why? If not, why not?

The UDI data format should be specifically defined by referring to the existing standards, compatible with the 2004 Rule on Bar Coding for Human Drug Products. However, the auto-ID technology, i.e. the data carrier, should not be specified. It is HIBCC's view that the data carrier technology used will depend on the type of device, scanning requirements and the feasibility, market penetration and benefits of using a specific technology.

FDA does have a role to establish guidelines for the use of certain technologies, so long as these guidelines are not overly prescriptive, in terms of specifying the technology, as this would stifle innovation, and may not be practical for all medical devices.

UDI BENEFITS AND COSTS**Question 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?

The UDI is an important component to improving patient safety where medical devices are used. However, while a cornerstone, the UDI alone is but one component of the systems required to improve patient safety through product traceability. A clear direction on the UDI provides consistency that will likely facilitate the development of IT systems, which in turn provides for uniformity across healthcare.

Equally important is that standard and consistent guidelines and specifications are developed for:

- Patient administration systems in relation to consumable and medical devices tracking, and adverse event reporting;
- Data models and specifications for the static and dynamic data required for the different applications;
- Purchasing and inventory control.

Also equally important is that IT investment in healthcare is increased in order that systems are developed and upgraded to take advantage of available technologies and standards. This investment will take some time, and improvements and benefits will be incremental in nature.

Question 16:

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

Most medical device companies are likely to comply with the appropriate guidance from the FDA. However, the guidance needs to:

- Support existing internationally recognized standards;
- Be practical and feasible for the class and type of device – e.g. surgical instruments as opposed to medical consumables such as dressing or gloves;
- Provide a range of feasible options (e.g. barcoding, 2-D and RFID), for the different classes of products.

Question 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?

Basic auto-ID technologies are commercially available and sufficiently mature for hospitals to implement today, provided that they invest in suitable software and hardware.

SYSTEM DESIGN AND SYSTEM ARCHITECTURE ISSUES

While the UDI is an important component to systems for achieving the desired benefits, it is only a small component of the overall system. The UDI alone will not contribute to these benefits. The other components that are required to achieve the desired benefits include, but are not limited to:

- Information management systems (software and hardware) with the appropriate functionality for the task required, e.g. materials management and purchasing software, enterprise resource planning systems, patient administration systems etc;
- Information systems designed to support the UDI and associated databases;
- Data model and data dictionaries incorporating the data required for the particular applications, referencing (or cross mapped) to the UDI;
- Systems and processes for “synchronizing” core product data from manufacturers catalogues through the entire supply chain;
- Systems integration – so that the different applications within healthcare using the UDI are integrated and not independent;
- Education, training and good management.

CLOSING AND CONCLUDING RECOMMENDATIONS

HIBCC would be pleased to offer the resources of the HIBCC constituency, as well as those of the HIBCC technical committees, as the FDA continues its assessment. We appreciate the opportunity to provide these comments. In conclusion:

- The design and implementation of the UDI should be based upon existing standards compatible with the 2004 Rule on Bar Coding of Human Drug Products. The FDA should recommend a format for the UDI based on existing standards ANS MH10 as the “umbrella standard,” under which the ANSI/HIBC-2 standards and GS1 standards are specifically recognized.
- The UDI should not specify a specific data carrier. Using existing standards, the UDI can be carried on all data carriers, including barcode, 2-D matrix technologies or RFID.

- The FDA should provide guidance on the data carrier (the specific technology e.g. barcode, 2-D matrix symbols or RFID), without being overly prescriptive. The guidance should include carriers where there is already good market penetration (such as barcodes), and that are ratified by existing ISO standards. For example, guidelines on where it is appropriate to laser-etch a 2-D symbol should be developed. HIBCC believes that surgical instruments that are re-usable, for example, are a good candidate for laser-etching a UDI.
- The FDA should develop implementation guidelines for the different classes of devices. For example, active implantable devices such as pacemakers should include the product identifier followed by the serial number as the UDI. Whereas other classes of devices should require the product identifier followed by the Lot or Batch number.
- While the UDI is an important component to introducing systems that improve patient safety and supply chain efficiency, it is equally important that this be put into the context of the overall system design, and the functions that will depend on the UDI.
- A basic data model that includes both static and dynamic data components required for systems should be developed and implemented in addition to the UDI.

ABOUT HIBCC

The Health Industry Business Communications Council® (HIBCC®) is an industry-sponsored and supported nonprofit organization. Founded in 1983 by numerous healthcare trade associations, HIBCC provides leading automated identification and e-business standards in support of safe and efficient information exchange, tailored to the specific needs of the global healthcare industry.

HIBCC's initial mandate, to develop a uniform bar code labeling system for product identification, resulted in the Health Industry Bar Code Supplier Labeling Standard (HIBC SLS). The HIBC SLS includes a variable length alphanumeric format for primary identification of medical goods, as well as the option for secondary information critical to healthcare processes such as lot/batch/serial number, expiration date and a secure link character.

A primary HIBC code is comprised of:

- i. A four-character **company prefix called the Labeler Identification Code (LIC)** which is assigned by HIBCC to labeling members;
- ii. A one to thirteen – character **product identifier** which is assigned by the labeling member;
- iii. A one-character **unit of measure** indicating the particular packaging level; and
- iv. A one-character **check digit**.

The structure of the HIBC SLS was designed to accommodate identification of multiple levels of packaging from pallets to individual items, and is based on a uniform data structure in order to provide consistency throughout global markets.

The HIBC code (the data) can be encoded on multiple types of symbologies (the data carriers), including linear codes such as Code 39 and Code 128, as well as reduced space symbologies such as Data Matrix and PDF-417, and within RFID tags. This ability to map data into 1-D, 2-D or RFID data carriers is critical in obtaining a solution across the wide variety of situations encountered within the healthcare environment.

Since its inception, HIBCC's broad mission has expanded to meet emerging industry requirements, and now also includes:

- Customer and vendor identification systems, such as the Health Industry Number (HIN) and the Labeler Identification Code (LIC);
- Internal hospital process labeling systems, such as the HIBC Provider Applications Standard (PAS);
- Electronic data interchange message formats, such as computerized ASC X12 EDI protocols;
- Uniform data repositories, such as the Universal Product Number (UPN) Repository.

HIBCC also plays a major advocacy and educational role in the health care industry. Its numerous Technical Committees and User Groups serve as the forum through which consensus can be reached in the development of e-commerce standards.

HIBCC and the HIBC Standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN) and endorsed by the International Organization for Standardization (ISO), EUROMED, the Advanced Medical Technology Association (AdvaMed) and the Medical Industry Association of Australia (MIAA).

HIBCC GOVERNANCE

The HIBCC Board of Directors, which oversees HIBCC operations and sets policy, is composed of individuals appointed from the ranks of our Member Organizations. These Organizations include:

Permanent Seats

- Advanced Medical Technology Association (AdvaMed)
- American Hospital Association (AHA)
- Federation of American Hospitals (FAH)
- Healthcare Distribution Management Association (HDMA)
- Health Industry Distributors Association (HIDA)
- Pharmaceutical Research and Manufacturers Association (PhRMA)

At-Large

Appointed on a rotating basis by the HIBCC Board to provide a balance in industry representation. Previous and current appointments include the following:

- American Society for Automation in Pharmacy (ASAP)
- American Veterinary Distributors Association (AVDA)
- Association for Healthcare Resource and Materials Management (AHRMM)
- Healthcare Information and Management Systems Society (HIMSS)
- U.S. Department of Defense (DoD)
- Web Enterprises