



To: The United States Department of Health and Human Services
Food and Drug Administration

Docket No. 2006N-0292
"Unique Device Identification; Request for Comments"

We thank you for the opportunity to review and comment on the above referenced document. The global Healthcare User Group, GS1 HUG™ (www.gs1.org/hug), comprises representation from major global pharmaceutical and medical device manufacturers, wholesalers, hospitals, regulatory bodies and trade associations. The GS1 HUG™ is striving for global standards for automatic product identification and is currently working with a number of regulatory bodies.

The GS1 HUG™ Leadership team has reviewed this document in detail, together with other GS1 HUG members and we would like to provide our comments. We are available to openly discuss these comments should you require clarification or additional information.

Sincerely

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The GS1 Global Healthcare User Group (GS1 HUG™)
Response to FDA
Unique Device Identification; Request for Comments

Summary

The GS1 Global Healthcare User Group (GS1 HUG™) recognizes the value a UDI system can add to the medical device supply chain and recommends a UDI system include GS1 Data and Data Carrier standards. The UDI should not be limited to one stage of technology, e.g. linear bar coding. Electronic Health Record systems should be designed to accept UDI data to link the patient with the medical devices used during their care.

A well-constructed UDI system would include: product identification that is globally standardized, the ability to accept evolving technology, the ability to globally access pertinent data associated to the medical device, and incentives for all members of the medical device supply chain to participate especially healthcare providers.

The use of GS1 Standards in healthcare is growing internationally. FDA should review the results of one UK NHS project in particular. The UK NHS Connecting for Health initiative maps GS1 bar codes into the Dictionary of Medicines and Devices (DM+D), the UK NHS repository for information pertaining to clinical products. This enables clinicians to scan the bar code on the physical product and unlock the electronic product file in the database to review the subset of data related to the queried products.

The GS1 Global Healthcare User Group would welcome the opportunity to discuss our response to the FDA Request for Comments at any time.

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?

Members of the GS1 Global Healthcare User Group recommend that a process for developing the system be accomplished by an industry consortium of stakeholders. The GS1 Global Healthcare User Group is an already existing consortium. In addition to medical device suppliers, health care providers, and trade organizations such as AdvaMed and EUCOMED in the GS1 Global Healthcare User Group, FDA and other regulatory bodies and healthcare ministries are encouraged to continue to participate and develop global standards. The membership of the GS1 Global Healthcare User Group is global.

In *Unique Device Identification; Request for Comments* (Federal Register Vol.71, No.155, August 11, 2006) FDA provides an example of a UDI for latex gloves. Five data elements are suggested:

- [1 - manufacturer] Acme (manufacturer number 12345)
- [2 - make and model] Great Latex Examination Gloves (product number 6789)
- [3 - size] Adult large (size number 012)
- [4 - how packaged] Box of 50 (quantity number 50)
- [5 - lot number] Lot

A unique device identification numbering schema should contain elements that identify [1] the company whose identity appears on the product's primary label, [2] an item number that identifies that company's product, and [4] an indication of package level. This UDI can be linked to a database associating other pertinent data. This pertinent data may vary according to product characteristics and customer needs. The data required for an in-vitro diagnostic device may be different from an implant.

The alternative schema that GS1 HUG™ members suggest is a UDI that includes the combination of manufacturer, item, and package indicator within the schema employed in the GS1 Global Trade Item Number® (GTIN). The GTIN is currently in use to identify a multitude of medical devices. The GS1

System includes Application Identifiers (AI) that precede and identify the subsequent data element. For instance, the GTIN is identified as (01) in both bar code and human readable interpretation.

Other required data elements that define usage and track/trace attributes such as expiration date, date of manufacture, lot, batch and/or serial number could be associated with the UDI but not necessarily be part of the actual UDI number.

The Agency suggests that the UDI includes a data element for unique attributes such as size or software version. In the latex glove example, this data element is identified as [3 - size] Adult large (size number 012).

If the UDI (combination of manufacturer – item – package indicator) were unique, persistent, and governed by a set of well-defined allocation rules such as the GS1 GTIN Allocation Rules for Healthcare, this attribute [3] would prove to be redundant. Medical device manufacturers use different part numbers to distinguish different sizes.

Dimensions must be qualified by an expression of their measurement system. Critical dimensions for medical devices are expressed not only in English and metric but also measurement systems such as gauge size, French size, or the 0-0 system for sutures (United States Pharmacopoeia).

Often there is more than one critical dimension for a medical device. For instance, the selection of a catheter is based on a clinician's judgment that a catheter's diameter and length would be optimal for insertion in the appropriate vessel. Including dimensions in the UDI would require complicated usage rules to govern the "order" of dimensions. For example, does English always precede metric? Does diameter precede length?

Given the complexity of medical device sizing, attribute [3] should not be included in the UDI schema.

Other data elements that define usage and track/trace attributes such as expiration date, date of manufacture, lot, batch, and/or serial number have their own application identifiers in the GS1 system: Expiration dates are identified with application identifier AI (17), manufacturing dates use AI (11), Lot numbers use AI (10), Serial numbers use AI (21). Each can be expressed in bar codes and their human readable interpretation.

As mentioned in the *ERG Final Report Unique Identification for Medical Devices*, the U.S. Department of Defense has also developed an identification system called IUID, Item Unique Identification. The IUID policy allows manufacturers to use the GS1 system as an approved form of IUID.

GS1 HUG™ members recommend that FDA follows the U.S. Department of Defense example, and allow medical device manufacturers to use the GS1 system to meet the identification and information needs of 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?

Many medical device manufacturers have voluntarily implemented forms of unique device identification.

In ensuring the safety of medical devices, FDA stated that they "would champion the development of a system to provide unique device identification." GS1 HUG™ members recognize the collaborative role FDA can play in this patient safety initiative. The GS1 HUG™ welcomes and encourages the participation of FDA in the GS1 Global Healthcare User Group to champion patient safety and public health in this space.

GS1 HUG™ members believe that if the UDI system were properly constructed, the medical device industry would voluntarily adopt the system with the goals to increase patient safety and reduce the stress of the healthcare professional. A poorly constructed UDI system without rules for number assignment, even if mandated, would not increase patient safety.

GS1 HUG™ members believe that a well-constructed UDI system should be global in scope. International standards must be incorporated into the UDI system. A US-centric system would be a burden on global manufacturers by forcing country-specific inventory segmentation.

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

Supply chain efficiency is an incentive to medical device manufacturers to establish a uniform, standardized system of unique device identifiers.

The focus of healthcare providers has historically been on diagnosis and treatment of patients. Patient safety can act as an incentive for hospitals to adopt UDI if the linkage between standardized data, data collection, and patient safety are clearly demonstrated.

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

Barrier: Cost.

If the redesign of labeling and packaging is required, the purchase of printing equipment, printing and verification of copy and machine-readable code, and other process changes will have a tremendous financial impact on medical device manufacturers. If technically possible, direct part marking on medical devices will also require biocompatibility and product integrity testing.

Barrier: Label Space.

Much device labeling has limited space to print information. To add a UDI in human readable, machine readable, or both formats simply cannot be accommodated with current labeling for many device products. Packaging and labeling would have to be redesigned for products.

Barrier: The Need for New Printing Equipment

Many device manufacturers out-source product labeling. A mandate to include UDIs with lot number, for example, could have a tremendous impact on this process, as some businesses assign lot numbers at the time of packaging. Medical device manufacturers would need to purchase printing equipment rather than rely on suppliers.

Barrier: The Need for AIDC Technology.

To mitigate cost and ensure the appropriate use of technology (i.e. 2D symbology versus linear bar codes), GS1 HUG™ members recommend that FDA champion a UDI system that does not specify a specific bar code technology. In the ERG report, the large number of medical devices in use in the clinical environment is mentioned. If FDA deems that a mandate is required, GS1 HUG™ members recommend an implementation period no less than five years.

There has been discussion that if FDA were to specify linear bar codes for devices as they did the hospital unit dose drug packaging, hospitals could use their existing base of linear scanners. GS1 HUG™ and several industry groups have recommended that hospital purchase image scanners. There has also been an increased use of two-dimensional symbologies such as Data Matrix code for use on patient identification wristbands. These symbols also require image scanners. GS1 HUG™ believes that the small, installed base of linear scanners in healthcare will be replaced by image scanners through attrition and as healthcare practitioners seek more reliability in their data collection devices. Image scanners are also designed to be backwards compatible; they can scan linear bar codes and 2D symbols.

Because of packaging size and readability issues, GS1 HUG™ members now use Data Matrix bar codes on many medical devices including sutures. We have seen hospitals such as Brigham & Women's also adopt Data Matrix.

Barrier: Direct Part Market – Technology and Environment of Use Issues

Some medical devices are provided in a non-sterile package that contains bar-coding information. However, to prepare this product for surgery, the packaging and product quickly become separated. Most of these non-sterile products are marked with a human readable lot number allowing traceability

to be maintained as long as hospital staffs document the information in the patient record. Automatically capturing this information would require that manufacturers provide the product in a sterile condition, which is expensive; or, manufacturers would have to mark the device with the UDI information. This is not practical due to the size limitations of some medical devices as well as the extensive amount of validation that must be conducted.

Devices that are structural supporting (e.g., orthopaedic and spinal implants) might be weakened if they are marked in non-compatible ways. Extensive validations would have to take place to ensure that the safety of these devices has not been compromised by the type, location and depth of the marking. Additionally, many of these devices are contained in surgical sets that are repeatedly sterilized through steam sterilization. This repeated sterilization can have a detrimental effect on the quality of the marking and may become unreadable after time. Again, extensive validations would have to be performed to prove out this process.

Barrier: The Need for a Database Infrastructure / Impact on Medical Device Suppliers

The request for comment envisions interfacing the unique device identifier (UDI) with computer databases with capabilities to access a reference data set linked to the UDI. However, unlike drug products and with the exception of OTC devices marketed in retail outlets, such infrastructure does not exist for medical devices.

The request for comment cites the ability to distinguish sterile and nonsterile implants as a potential use of UDIs. Without the infrastructure to hold this information, the UDI, alone, would not accomplish this goal.

Globally accepted data pools and the Global Data Synchronization Network do exist to synchronize data among trading partners. While mainly populated by retail items, several GS1 HUG™ members intend to add medical devices and supplies. It may be more efficient to modify an existing infrastructure than to create a U.S. / FDA centric system. The GS1 HUG™ invites FDA to explore GDSN as a medical product information repository.

The request for comment identifies UDIs to identify compatibility issues, such as devices, which can be used safely with magnetic resonance imaging (MRI) systems. Yet without links to patient charts from one facility to the next, such processes could not occur. The lack or adequacy of database infrastructure is a barrier to the establishment of such a UDI system. Further, the cost to the device industry to maintain such information considering the shorter lifecycle of some device products versus drugs and the variety of medical devices compared to drugs must be considered.

Barrier: The Need for a Database Infrastructure / Impact on Healthcare Providers

The most significant barrier will likely be the hospitals' required infrastructure and acceptance of the new processes and associated capabilities that would need to be developed. They would require systems and equipment installation, validation and integration to utilize any UDI implemented at the manufacturer level.

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?

Many GS1 HUG™ members identify their packaged products with bar codes. These bar codes comply with global industry standards. These bar codes typically contain a primary product identification (GTIN or UPN) and lot number and expiration dates if applicable. Depending on the substrate and surface area available, bar codes are linear or 2D. GS1 HUG™ members use direct part marking when appropriate and technologically feasible. GS1 HUG™ members do comply with the US DoD Item Unique Identification (IUID) policy. The DoD UID construct recognizes the GS1 SGTIN and GS1 GRAI data standards as equivalents to the US DoD UID for medical equipment.

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?

A basic, globally accepted unique device identifier can be used for all medical devices on a voluntary basis. This identifier, such as the GS1 GTIN, could include a minimum set of data elements, e.g.

manufacturer identification and product part number and package indicator. Where the unique identifier is printed (directly on the part or each level of packaging) as well as the inclusion of other attributes (lot, serial number, or expiration date) should be determined by the risk associated with the use of the medical devices. GS1 HUG™ members recognize that identification and tracking and tracing requirements differ. Broad categories with different requirements may include: active implantable devices, implantable devices, sterile devices, and electro-mechanical devices.

Regarding direct part marking, the GS1 Global Healthcare User Group believes that medical devices are extremely diverse in size, materials, processing, use and criticality. A mandatory bar code rule for the direct part marking of medical devices will increase cost and complexity for users, with little assurance of improving patient safety.

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?

The type and size of the device and the environment of use are important considerations. Other factors to consider include when and where do clinicians select and authenticate product. The physical size and material composition of the medical device may dictate whether or not the medical device can be directly marked and decoded by users. The size of primary packaging may also limit the amount of additional information or form of machine-readable code that can be printed on the package. In this response UDI's are only being considered for unit level packaging, or direct part marking.

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)?

GS1 HUG™ members continually research the use of marking medical products and packaging such as digital printing, laser ablation, and RFID. New technologies are emerging and AIDC product life cycles are short. For this reason, GS1 HUG™ members do not believe that the UDI should be limited to one stage of technology.

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?

GS1 HUG™ recommends a minimum set for the UDI: manufacturer identifier, item identifier, and package identifier. If FDA accepts the GS1 system as supportive of UDI, then lot, batch, serial number (SN), and expiration dating can also be present. Several GS1 HUG™ members already serialize product using the GS1 SGTIN data standard.

The serialization of certain medical devices such as some implants may also provide benefits including the inclusion of specific implant data (UDI and SN) into Electronic Health Records. The serialization of clinical instruments, when used in a well-designed tracking process, may prevent cross contamination and disease transmissibility. The serialization of other medical devices may deter counterfeiting and improper reprocessing.

The UDI system should not attempt to categorize medical devices across manufacturers. Many medical devices cannot be compared generically as unique features affect the usability and performance of the device. For example, medication infusion pumps designed for certain care environments and specific clinical interventions. An ambulatory pump used for Total Parenteral Nutrition (TPN) in a patient's home is not interchangeable with a Patient Controlled Analgesia (PCA) infusion pump used in the acute care hospital, yet both of these devices would fall under the "category" of "infusion pump". Categorization of medical devices would compromise patient safety, if both pumps had the same category and, therefore, viewed as interchangeable.

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?

The UDI system should recognize the industry-accepted identification systems. See table as an example.

Issuing Agency	UDI Acceptable Data Formats
GS1	GTIN Application Identifier AI(01) GTIN + Serial Number: AI(01) + AI(21) SGTIN in EPC (Electronic Product Code)

The UDI system should also enable the clinician to submit the UDI to a web site and obtain information appropriate to the selection, authentication, and use of the medical device.

GS1 HUG™ members already make their product instructions for use available electronically through web sites. GS1 HUG™ agrees with FDA and sees value in one common portal for all medical device data; similar to those maintained by the National Library of Medicine such as www.clinicaltrials.gov and <http://dailymed.nlm.nih.gov/>. In other countries like e.g. Australia national product catalogues are developed in cooperation of the national authorities and the local GS1 Member organization.

GS1 HUG™ members recognize that standards (Adobe® Acrobat *.pdf) and processes such as version control need to be developed to maintain the timeliness and accuracy of data. GS1 HUG™ would welcome an invitation to participate in the development of these standards and processes.

There are viable data pools and systems dedicated to commercial transaction such as the GS1 GDSN system and the Global Healthcare Exchange (GHX). The focus of a healthcare data pool (including medical devices) should include clinical information.

A healthcare industry consortium that includes manufacturers, distributors, and healthcare providers should be formed to develop system architecture and policies for storing and sharing data. The GS1 Global Healthcare User Group is an industry consortium that is already in existence and is global in scope.

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?

Yes, human readable UDI data should appear once where the UDI is required. The nature of the device and the maturity of marking technologies dictate whether any device can be directly marked. FDA should recognize that changes to the product itself could be more difficult than changes to packaging. The manufacturer, based on customer demand, should determine whether or not a product could be marked directly. GS1 HUG™ members believe that the development of industry standards for identification such as those maintained by GS1 can help the healthcare provider incorporate UDI into their electronic health record and materials management systems.

The physical size and material composition of the medical device may dictate whether or not the medical device can be directly marked. New direct part-marking technologies are emerging and product life cycles are short. For this reason, GS1 HUG™ members do not believe that the UDI system should be limited to one technology.

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 codes recommend, 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?

No, the UDI should not be limited to a specific technology.

FDA should allow the membership of the proposed Issuing Agencies to decide. GS1 members use a rigorous process, the Global Standards Management Process (GSMP) to approve appropriate technologies. Assuming the GS1 GTIN is accepted as a form of UDI, the GS1 standard carriers should be accepted: GS1-128, RSS, and Data Matrix.

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.

One benefit would be for hospital personnel to accurately and automatically verify that they have the correct product in its correct configuration. Poor data capture without automatic verification compromises the ability of hospital personnel to perform device recalls accurately. Poor data capture can equate to product escape. Most current hospital systems rely on manual data entry.

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.

The cost varies depending on the solution. If the solution includes standards already in use, i.e. GS1 standards, the cost will be much less than if a non-standard or totally new standard is employed. Regarding technology, bar coding will cost less than RFID.

Set up costs and timelines will vary according to the device and production volumes. The overall financial impact to the medical device industry would be significant.

Certainly, UDI on packaging would require the installation of digital printing systems, validation of software and processes, and management of raw materials. All effort should be made to avoid scrapping valuable and often allocated materials. For direct part marking, product redesign, testing associated with biocompatibility and sterilization processes increase the cost and timelines.

Including data in the UDI format apart from the GTIN (GS1 Global Trade Item Number) would increase costs dramatically.

For some product lines, the entire distribution model and cost structure would require change.

ERP systems would also be affected to optimize the use of UDI for track and trace.

ERG has summarized that there are several potential technical difficulties, which will require significant capital investments and expenditures depending on the scope of UDI requirements. Although such initial costs would be borne by the manufacturers and distributors, over time these costs would be shifted to the patients, private insurers, and government.

15. If you have already implemented a form of unique identification on your medical device labelling, 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?

Many GS1 HUG™ members, including Brigham & Women's Hospital, have implemented forms of unique identification that include the use of both linear and Data Matrix bar codes. Automatic identification and data capture technologies have been implemented to increase supply chain efficiency and to comply with directives from other healthcare ministries across the globe.

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

AIDC technology acceptance will accelerate in healthcare. GS1 HUG™ sees a clear linkage of unique product data to the Electronic Health Record. Acceptance of EHR technology will lead to acceptance of UDI. The establishment of organizations such as the GS1 Global Healthcare User Group (see

www.gs1.org/hug/) and the National Alliance for Healthcare Information Technology (see www.nahit.org) accelerates the use of AIDC in healthcare.

17. From your perspective, what are the obstacles of using a UDI system in your location?

The most significant obstacle would be the rate of acceptance and compliance by hospitals. A poorly constructed UDI system that would not allow manufacturers to use existing forms of UDI such as the GS1 GTIN would cause manufacturers to renumber all of their products and pose substantial administrative and financial burden.

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?

GS1 HUG™ members believe many hospitals are installing electronic medical administration record systems including scanning at the bedside. We see electronic health record systems as the logical location for UDI data. If the UDI system is well constructed, hospitals could implement EHR systems and UDI systems in tandem. Another trend in hospitals is emphasis being placed on medical error prevention and quality of care improvement. Use of UDI may enable these professionals to increase their accuracy of MDR reporting and tracking product subject to recall.

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?

A well-constructed UDI system will allow the usage of the machine-readable technology most appropriate to the product and the environment of use. For many medical devices, this would be 2D bar coding such as Data Matrix. Hospitals should purchase image-based scanners if they have not already done so.

If the proposed UDI system allows the use of GS1 data standards, this would enable most existing material management systems to accept GS1 data as default values. If a UDI system establishes new key UDI fields, then the software that hospitals use to manage inventory and to manage patient data would need to be revised; adding cost and impeding hospital acceptance.

Costs that hospitals may find significant include the software and the skilled labor to install and maintain these systems. Software, labor, and the cost of changing processes are significantly higher than the cost of data-collection hardware.

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class 1) or next most serious (Class II) recalls would have access to and an ability to capture UDI information help you to respond?

GS1 HUG™ membership does include healthcare providers who see supply chain efficiency using the GS1 system. Many GS1 HUG™ members use UPNs or GTINs with lot or serial numbers to identify product in recall situations.

Other Comments.

Dr. Kessler posed three questions in the public meeting:

A. Should the bar code include a human readable element?

Human readable data should appear once on the label.

B. Should the numbering scheme be an intelligent numbering scheme?

The UDI should include no more intelligence than the current GTIN holds now, namely, package indicator, manufacturer identity, and product item number.

C. What would the preferred data structure look like?

The GS1 Global Trade Item Number (GTIN).