

**Hand**

PRODUCTS



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November 7, 2006

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

Re: Comments Concerning a Unique Device Identification System  
(Docket No. 2006N-0292)

Dear Sir or Madam:

On behalf of Hand Held Products, Inc. (Hand Held), the undersigned submits these comments in response to the Food and Drug Administration's (FDA) request for comments regarding a unique device identification (UDI) system.

Hand Held was founded in 1972, and is today a leading manufacturer of reliable, high-performance data collection and communication solutions designed specifically for mobile, in-premise, and transaction processing applications. Headquartered in Skaneateles Falls, New York, USA, Hand Held employs over 1,000 people worldwide and operates in every major market of the world. Hand Held's success has, and will continue to be, based on delivering the highest level of personal service to our customers.

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By investing in Hand Held Products' hardware, software and professional services, our customers are able to reduce costs, improve operations, enhance customer service, position their companies for future growth – and achieve a rapid return on their investment.

Hand Held Products endorses the implementation of UDI system to further advance the efforts of healthcare in reducing patient errors and cost associated with those errors.

Hand Held is providing responses to the specific questions as follows:

1. 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's role should be to create the overall ruling on UDI for medical devices and also support the development and implementation of the system itself. However, the FDA should not be involved in the administration. A voluntary system would not be as effective in achieving the desired goals and potential benefits and thus use of the system should be mandatory.

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

A uniform, standardized approach to unique medical device identifiers will empower the healthcare industry to implement systems to ensure consistency, accuracy, and predictability for the entire healthcare system. Some key areas of benefit will be in the reduction of counterfeiting, facilitation of medical device reporting, enablement of more accurate recalls, and identification that the correct device is being used. This is a critical need for automated patient safety systems; e.g., a handheld computer can be used to communicate programming instructions to an infusion pump at the point of care but the system must be able to identify the device that will administer the medicine (device manufacturer, model, and

firmware revision—these could be encoded explicitly or simply using a license plate look-up scheme). If the handheld computer can capture the ID of the medical device, then the programming of the proper administration can proceed automatically.

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

The biggest barrier, if left to its own devices, will be obtaining agreement from all the interested parties on the data that should be encoded and setting up a system to administer and maintain the data base. To overcome a portion of the barriers the FDA needs to issue a mandatory ruling.

4. 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?

Yes, all devices should be labeled. The UDI should be considered for all devices since this would allow for a predictable robust system. The type of labeling should take into consideration what the economic impact and physical features of the device are before determining the label requirement (RFID tag, paper label, direct part marking, etc.) All devices should be labeled consistently to further advance the patient safety initiative.

5. 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.

Hand Held Products has been a technology agnostic manufacturer of linear (1D) and two-dimensional (2D) bar code scanners since 1972 and has supplied samples of dual technology reading

devices since 2004 (RFID and bar code scanning in one device). Today, two-dimensional symbologies are ideal as data carriers for medical devices but we must take into consideration where technology will be in the implementation process of this mandate in three to five years. Required information such as, item number, lot, batch, serial number can all be contained within a two-dimensional code and/or a RFID tag. Hand Held is in a position to support an initiative which defines the data content for the UDI, but lets the application determine the most appropriate data carrier (i.e.: 1D bar code, 2D bar code or RFID).

A number of hospitals have implemented a new patient identification system that uses two-dimensional bar codes on wristbands. It was found that nurses would frequently bypass the automatic safety process because it was too difficult to use, largely due to the use of linear bar codes that are printed in a small area. 2D matrix codes, such as Aztec Code and Data Matrix are strongly recommended for any application where the marking area is small, or the number of data characters exceeds a short license plate.

Hand Held envisions a patient safety system where the nurse can carry a single device that would be used to effortlessly read the patient ID codes on the patient wristband, and the device ID code on the medical device. To the extent that the devices can be marked with a 2D matrix bar code, this vision is within reach. For example, an Aztec Code symbol having an X-dimension of 15 mils can be read by a nurse from about one inch to 8 inches from the code. Such a symbol could be printed to contain up to 60 characters in an area of 0.4 x 0.4 inch. An Aztec Code symbol having an X-dimension of 25 mils can be read from about one inch to 11 inches.

It will be an advantage to these applications if the choice of data carrier is specified in a way that allows a single reader to be carried by a nurse and to read all of the codes in the patient safety system.

6. 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?

After the FDA has mandated the ruling and determined the minimum data content, the overall administration of the UDI system (including standards and procedures dissemination, data set control, maintenance and access, etc.) should be by an international standards organization or industry organization that either represents the AIDC (Automatic Identification and Data Collection) industry such as AIM Global or GS1 or by a health or medical devices organization such as AdvaMed or HIBCC. This recommend is based on the commercial success of the UPC code in the retail market.

7. 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?

Use of both the AIDC technology (such as bar code) and a human readable representation of at least a minimum part of the data contained in the AIDC technology is preferred to allow for manual identification if the automatic method is not available. This is not unlike the human readable characters used in the majority of bar code applications as a back up for use in manual data input where needed or the use of bar code technology as a fail safe redundancy for RFID technology. If physical space is adequate, use case or maintenance allow, and proper application or marking techniques can be found for the device, it would assist in traceability and security if the UDI was found on or securely attached to the device itself as well as having a form of redundancy in a human readable representation.

8. Should 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.

The UDI should not be based on a specific technology, but should give preference to a group of technologies that are compatible with other healthcare initiatives, such as patient safety. The ruling by the FDA should determine the required data content, allow for the extension of data features and give examples of preferred data carriers (eg. 2D bar code, RFID). The ruling by the FDA should allow for the application using the UDI to determine the most appropriate data carrier. The rationale for this position is that the limitations set for the drug bar code rule have put constrictions on the amount of potential data that could be available to the industry. One example is a drug recall. Only encoding the NDC number in a linear bar code does not supply enough information to identify a recalled drug. Medical devices are vastly diverse and manufactured by multiple companies. In the instance of a recall, it is imperative to identify the correct manufacturer and specific recalled device. The data carriers chosen for the application (i.e. linear bar code, two-dimensional bar code, contact memory button, smart card, RFID, mag stripe) should not limit data content. For example, because 2D matrix bar codes make better use of space than linear bar codes, they could have enabled the encoding of the NDC number plus lot number and expiration date on a unit dose package. Many manufacturers can supply reading devices that are capable of reading both linear codes and 2D matrix codes. As previously described, Hand Held has used a 2D bar code symbology known as "Aztec Code" (a standardized, public domain symbology) successfully on a patient wrist band for various patient safety initiatives.

Aztec Code was selected from all existing Auto ID technologies because it was the easiest for the nurse to use, given that the space that was available for marking was small. Data Matrix would have been the second choice for that application.

There is a significant advantage if the same reader can be used to capture all the data in a patient safety system (patient ID and medical device ID). The same device is also capable of reading the RSS codes on the unit does packages.

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

A UDI system will fold into the current patient safety initiatives within the hospital environment with little resistance over a three to five year period after the effectivity date. Hospitals will struggle with existing devices currently in use. At the clinic and physician office level there has been little or no automation adoption but will begin over the next five to seven year period. Continuing economic pressures to reduce healthcare costs and improve patient safety will speed up the adoption. Until the healthcare market realizes such savings and patient safety, adoption will be slow unless there is a significant compliance event that mandates the use of the UDI for particular applications. Some of the key benefits that a UDI system will produce: accurate recall event, device reporting, more accurate inventory control, reduction and reporting of adverse drug events, deterrent of counterfeit devices, and aide in maintenance records.

#### Conclusion

Hand Held Products supports a mandate for minimum data content in a UDI system with the allowance for additional data features where appropriate. The data carrier (i.e. linear bar code, two-dimensional bar

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code, RFID, mag stripe, contact memory, smart card) should driven by the device and its application in healthcare. A global UDI system is recommended to reduce the economic impact on medical device manufacturers.

We hope that you find these comments useful and welcome the opportunity to further comment on the agency's development and implementation of a UDI system.

Sincerely,  
HAND HELD PRODUCTS, INC,

A handwritten signature in black ink, appearing to read "George S. Smith, II". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

George S. Smith, II  
VP/General Counsel