

Comments on docket 2006N-0292 Unique Device Identification.

November 4, 2006

For many the same reasons the FDA ruled that drugs be identified with EAN-UCC (now GS1) or HBICC bar codes (linear bar codes), I believe any rule applied to medical devices should, at a minimum, include the same linear bar code requirements. This does not mean that the FDA would be unwise to require RFID identifiers on devices. However, RFID chips should augment, rather than displace barcodes.

My reasons are as follows:

Hospitals are rapidly adopting bar-code point-of-care (BPOC) systems for medication administration, transfusion, and lab applications. Given the adoption rate of this technology, it is reasonable to assume that before the decade ends, most of America's hospitals will be utilizing BPOC for virtually all medication administrations. Hospitals possessing BPOC will be able rather easily to expand system functionality to incorporate the scanning of medical devices without having to incur the expense of adding RFID-reading devices and the infrastructure required to support them.

It will be a long time before *most* medications have RFID labels and it is highly doubtful that some unit-dose oral solid medications will ever have them (Tylenol or Aspirin tablets for example).

Certainly the day will come when many medications have RFID chips embedded in their labels. However, rather than displacing, these chips will augment barcodes. This means that even in an RFID world, barcodes will continue to have their place and scanners utilized by caregivers will come with both bar-code and RFID readers built in.

A History Lesson

When the early developers of bar codes sought advice from a professor at MIT, they explained a problem. While machines could read barcodes, humans could not. The professor inquired about what exactly a barcode was. The developers said it was a number represented in bars and spaces. The professor wisely suggested they print the human-readable numbers under the machine-readable bar codes. They did—right where the numbers reside to this day. Thus bar codes are redundant identifiers. This means that if for some reason a

bar-code scan is unsuccessful, the number beneath it becomes the source of identification.

I learned this from an expert from the AutoID brain trust at MIT, who concurred that when RFID chips appear en masse on retail products, they, like bar codes, will be redundant identifiers. Bar codes will remain, along with human-readable numbers, I might add.

Long before all institutions can afford RFID infrastructure, if medical devices have linear barcodes, common hospitals utilizing BPOC technology will be able to exploit the benefits of medical device identification. **Thus, at bare minimum, I encourage the FDA to require that medical devices should have a linear bar code on them.**

I understand that RFID chips can carry much more information than barcodes—valuable information, I might add. Therefore, the FDA would need to decide what essential information should be included in the bar code. This information could be redundantly added to an RFID chip along with any other useful information.

We have precedent for this with the medication bar-code ruling. The FDA wisely required that linear barcodes must include the NDC number. While lot numbers and expiration dates were not required, manufacturers were allowed to include this information in more complex symbologies if they so desired.

Thank you for the care with which you are weighing the comments you have received.

Sincerely,

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Post Script:

Simple bar codes have some advantages over more sophisticated RFID chips. For one, barcodes are more reliable as RFID chips may explode, rendering them unreadable. Furthermore, the fact that RFID is a proximity technology is both an advantage and disadvantage. For example, a nurse may have five medications in her hand, which an

RFID reader in proximity could read simultaneously. However, if the system informed the nurse that one of these medications did not belong to her given patient, the nurse would have to move all five medications out of the device's range of read and then move each item in and out of range, one at a time. This would be inefficient and get in the way of the caregiver's mission. With bar codes read by line-of-site readers, the nurse can move through the five medications one by one without any inconvenience.

The latest technology is not always the appropriate technology.