Docket No. 02N-0204

Permanent Bar Code Labeling
For
Healthcare Medical Devices

Submitted to the FDA
By
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Position: That the FDA should select the EAN.UCC system as the healthcare product marking system, rather than a particular Symbology. .

I would like to thank the Food and Drug Administration for this opportunity to talk about patient safety. The proposed rule to mandate bar coding at the unit dose level is essential to improving the quality of patient care. Medication errors are deadly and costly, and can have a devastating impact on the healthcare industry.

Rather than ask the FDA to select a single Symbology, such as Reduced Space Symbology or Composite Symbology, I instead ask you to select the EAN.UCC System for the bar coding of all healthcare products in the United States.

Bar coding of all healthcare products down to the unit dose has been the goal of the EAN.UCC System. The Uniform Code Council and EAN International developed Reduced Space Symbology and Composite Symbology specifically to address this need. Manufacturers, healthcare providers, and leading industry groups have been working with

us for the past five years to develop a solution that brings greater automation, accuracy, and information detail to small healthcare products.

What is important to note is that Reduced Space Symbology and Composite Symbology are just the latest tools in a truly global system of commerce. The EAN.UCC System is used by nearly one million companies conducting business in 140 countries around the world. These standards for physical identification and electronic communication allow companies to bring greater accuracy and efficiency to products and the corresponding flow of information.

The EAN.UCC System is used by 23 major industries worldwide and provides a global language for companies to identify products, assets, shipping containers, and locations throughout the supply chain. This system has a strong presence in the healthcare industry. Nearly ten percent of the Uniform Code Council's membership comes from healthcare, including manufacturers, retailers, distributors, and healthcare providers. The overwhelming majority of all products purchased by hospitals utilize the EAN.UCC System. Whether it is linens, cleaning supplies, medical/surgical products, food, pharmaceutical products, beds, or even flowers- everything a hospital purchases is encoded with our system of bar codes and standards.

Wherever the healthcare industry has a presence- in the hospital, in drug stores, in grocery stores or any retail store selling OTC products- the EAN.UCC System is at work. For nearly thirty years, the Uniform Code Council has been providing bar code

innovations that have benefited consumers and industry alike. By selecting Reduced Space Symbology and Composite Symbology, the healthcare industry will be able to utilize their existing investment in the EAN.UCC System. This will cause the least disruption to the healthcare supply chain. It will also allow the industry to implement the FDA mandate faster. Radical system upgrades will not be an issue, so the industry can quickly respond and address the need to reduce medical errors.

As part of the EAN.UCC System, Reduced Space Symbology and Composite Symbology are globally recognized standards. Universal guidelines have been established for the placement of symbols, density and texture, and ANSI grade of the symbol for commercial use. RSS and Composite Symbology can be printed, scanned, and verified by readily -available commercial equipment. Two of the leading scanner manufacturers, Symbol Technologies and HHP tell us that there are an estimated 2 million scanners in the commercial marketplace today that can read RSS or Composite. (See attached) The Uniform Code Council knows of at least two major pharmaceutical firms that are now labeling or about to label their products with Reduced Space Symbology and Composite Symbology for commercial distribution.

It is also important to note that the Uniform Code Council is a neutral, not-for-profit standards organization. The Council does not sell bar codes, software, scanners or proprietary solutions, so there is no vested interest in promoting RSS and Composite to the FDA today. Our system is open and voluntary, and the patents for RSS and Composite, like all of our standards, have been placed in the public domain, freely

available to any company that wishes to use them. The reason the EAN.UCC System is globally successful is that any company, in any industry, anywhere in the world can use our bar code and electronic standards and dramatically improve the accuracy, speed, and efficiency of their business.

Accuracy is essential to reducing medication errors. And one of the important benefits of RSS and Composite is that the healthcare industry will be able to utilize their existing supply chain infrastructures through the use of the EAN.UCC System. For example, costly re-labeling of products will be eliminated for overseas distribution, and the technical impact on systems will be minimized. This will allow the industry to achieve significant improvements in medication accuracy while controlling costs. As our bar code solutions have demonstrated in every other major industry, the efficiencies that will be gained will allow the healthcare industry to dedicate more resources to improving the quality of patient care.

In closing, we believe the FDA should pick a system that improves patient safety, not just a particular bar code. I am confident that the Uniform Code Council and the EAN.UCC System can provide the tools and global strength to help the FDA improve the quality and safety of patient care in the United States.

ATTACHMENT !Symbol Technologies

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The information below is intended to help the FDA assess the impact of a decision to mandate either:
1) RSS only (as a cost/benefit tradeoff, for capture of only the NDC codes at bedside), vs
2) RSS-based Composites (NDC in linear portion, still allowing the above cost/benefit tradeoff, and Lot and Expiration Date in a line-scannable 2D portion), vs
3) Data Matrix (with all info in a 2D portion that can be scanned only by 2D imagers).

Given the above choices, one of the key questions becomes:
Is there a significant installed base of scanners and portable terminals that cannot read Data Matrix (and cannot be upgraded to read Data Matrix), but that can read RSS (or RSS and Composites), or that can be field-upgraded (ie, software change only) to read RSS or RSS/Composites?

We've looked at the product breakdown this way:
* we've included U.S. Sales figures only, for Symbol-branded products only
* we've excluded any units sold prior to 1998
* we've excluded imager-based products, because they are relatively unaffected by the symbology choice
* we've made four categories, for:
  - products currently shipping with RSS and Composite capability (installed base, plus projected shipments through December 2002)
  - products currently shipping with RSS capability only (installed base, plus projected shipments through December 2002)
  - additional products (again giving the projected installed base by year-end) that we've determined could support RSS via cost-effective software-only upgrades (ie, without physically opening up the units or replacing any parts).
  - additional products that could support RSS and Composites, under the same criteria given above.
* we've excluded several product lines where, although they may prove to be field-upgradeable, it would take some R&D work on our part before we could firmly state that they are upgradeable. Thus, the 'upgradeable' numbers below are deliberately conservative ones. This is especially true for the Composites category: for example, even though our largest-selling single-line laser scanner ships today reading PDF417, we did not count it in the 'upgradeable to Composites' category, because the R&D work for that assessment has not been done.

Under the above set of criteria, the figures provided by Symbol Marketing are as follows (note that units are never double-counted in more than one of the categories below):
* Products shipping with RSS-and-Composite capability today, projected installed base by year end: over 40,000 units.
* Additional products shipping with RSS-capability today, projected installed base by year end: over 380,000 units.
* Additional products determined to be s/w upgradeable for RSS/Composite, projected installed base by year end: over 31,000 units
* Additional products determined to be s/w upgradeable for RSS, projected installed base by year end: over 1,280,000 units

Thus, we expect that, by year end, there will be nearly 1.7million Symbol scanners or scanning terminals deployed in the US that cannot read Data Matrix and cannot be upgraded to do so, but that either read RSS today or could be cost-effectively upgraded to do so. Of those 1.7million

units, over 70,000 are also Composite-capable (either today, or could be software-upgraded to read Composites).

Best Regards,
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ATTACHMENT 2 HHP STATEMENT

July 24, 2002

HHP's, (formerly known as Hand Held Products, a Welch Allyn affiliate) policy has been to support all commercially viable public domain barcode symbologies. HHP supports the Reduced Space Symbology (RSS) family plus the EAN•UCC Composite symbology using the RSS linear symbol used for capturing information like product lot numbers and expiration dates.

HHP began its support for the UCC's RSS symbology as early as 1997 and officially included it in its scanning products in early 1999. HHP was clearly the first manufacturer to support the UCC with this important symbology.

HHP currently has an install base supporting the RSS linear symbology that exceeds 500,000 scanning products; HHP also has deployed over 100,000 scanning products that support the EAN/UCC Composite with the RSS component. Many products released prior to 1999 may be upgraded to support the RSS symbology with a simple, and free, download from HHP's website (www.hhp.com).

Today, all HHP linear and area imaging product lines support both the RSS and EAN•UCC Composite symbologies. These products include the hand held scanning suite of the **IMAGETEAM™ 3800** linear imagers and the **IMAGETEAM™ 4410** 2D imagers plus it's **Dolphin®** line of portable data terminals.

For further information, please contact:

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