

**Baxter**

Home

Patients,  
Families & DonorsHealthcare  
Professionals

Customers

Corporate Info

- News Room
- Investor Information

Careers @ Baxter

Doing Business  
With Baxter

- Customers
- Suppliers
- Community

## ENLIGHTENED<sub>HRBC</sub> Bar Code Technology

### Technical Background / Fact Sheet

#### Why is bar coding needed?

Research cited by the Institute of Medicine three years ago estimated that 44,000 and possibly up to 98,000 patients die in the United States every year from preventable medical errors in hospitals (1). Even using the lower number, that puts medical errors as the eighth leading cause of death in the United States. The Food and Drug Administration (FDA) believes that 30 to 50 percent of these deaths are associated with errors involving the use of FDA-regulated medical products, drugs, vaccines, blood and blood products, and medical devices (2). Preventable morbidity and mortality related to drugs alone increases the nation's health care bill by more than \$136 billion a year (3).

As part of its focus on improving patient safety, the FDA held hearings this summer to consider mandating bar codes on all human drug, biologic and blood products down to the unit of use. Including bar coding on medication is recognized as one important step toward reducing medication errors and increasing patient safety as well as operational efficiency in our hospitals and other health care locations. One challenge is how to effectively print bar codes, and especially bar codes with lot number and expiration date, on flexible IV containers. Flexible IV containers are used extensively in all hospitals and alternative site health care facilities.

#### Why is there not a simple solution?

The print quality of the bar code is critical to the success or failure of the bar code application. The smaller the bar code, the higher the printer resolution must be to obtain a readable bar code. Hospitals have expressed a need to have product bar codes on the "unit of use," not just the case or bulk package. To illustrate the enormity of the task, it would be as if in the retail market each individual tablet of aspirin sold would have a bar code, not just the bottle or outer box.

Today, many customers who are using bar code-based point of care or inventory management systems must re-label products that are not bar coded by the manufacturer. Re-labeling products creates the potential for adding labeling errors to the system. Products already labeled with bar codes save time, money and reduce

potential labeling errors. Many health care providers are using outside re-labelers to repackage drugs in unit of use configurations with bar codes; however, this re-packing and re-labeling can add up to \$0.09 per package (4). In addition, in recent FDA testimony, a panelist gave the example of an institution dispensing 2 ½ million doses per year with a 99.9 percent accuracy rate for repackaging. Even with that accuracy rate, repackaging would still introduce 70 new errors a day from repackaging (5). For these reasons, repackaging is not a viable solution for placing bar codes on medication.

#### **How a bar code works**

Bar codes typically do not contain descriptive data. Instead they act like a license plate on a car. They feature an identification number used to search for specific information in a database, such as associated descriptive data and other pertinent information. Bar codes are simply machine-readable codes representing any numerical or text data.

The mechanics of bar codes are similar to Morse code, but instead of using a pattern of dots and dashes to represent numbers and letters, bar codes use a combination of wide and narrow bars and spaces. By varying the width and patterns of the bars and spaces, a language or symbology, is created to represent numbers, letters and punctuation.

Bar code scanners are used to retrieve information encoded in bar codes. Scanners work by using a light source to illuminate the bar code symbol. The dark printed bars absorb light and the white background spaces reflect light back to the scanner. This principle explains why most bar codes are composed of black bars on a white background.

#### **Types of Bar Codes**

There are currently three main types of bar codes used in the market. Linear bar codes are the familiar bar code symbols that encode a unique product identification number or name. The more characters the bar code must encode, the larger the bar code needs to be. Two-dimensional bar codes, or 2D bar codes, are a newer type of bar code that can hold larger amounts of information in less space than a traditional linear bar code. The third main type of bar code is the REDUCED SPACE SYMBOLOGY (RSS) (6) or COMPOSITE SYMBOLOGY (7). The Uniform Code Council (UCC), a not-for-profit organization that builds consensus around standards, developed RSS as a way to place bar codes on objects that are too small for traditional linear bar codes such as individual tablets, vials, ampoules and pre-filled syringes.

#### **Why including lot and expiration date is important**

The inclusion of lot numbers and expiration dates can help to reduce the incidence of

medication errors while improving operational efficiency within an institution. By including lot number and expiration date, a point of care system can notify the clinician if a product has expired or if a recall has been issued before a patient receives the product. While patient safety is everyone's chief concern, bar coding products and tracking usage also helps institutions to streamline their operations. By tracking lot number and expiration date against inventory, an inventory management system could alert the users about a product that is nearing expiration and that should be used immediately to reduce waste. Point of care systems can also help institutions track and more accurately bill patients as well as to more efficiently order and manage their inventories.

### **The problem**

There are many challenges that manufacturers of IV solutions must overcome in order to print effective bar codes on their products. These include finding a printing technology that can withstand the IV container manufacturing process, including heat sterilization, and still be scannable; finding a technology that has the flexibility to accommodate variable data such as lot number and expiration date; and identifying an ink that meets FDA requirements.

IV manufacturers print directly on clear flexible IV bags, which in some cases are terminally steam sterilized at temperatures over 248 degrees F (121 C). Sterilization can cause the bag to stretch under heat and pressure, causing some distortion to the printed bar code. Also, since the bar code is printed directly on the IV bag, the inks must not interact with the drugs or solutions inside. The safety of the inks must be qualified and then submitted to the FDA for approval. Finally, the vast majority of IV bags produced in the United States are printed with a low-resolution printing technology called "hot stamp" printing. Hot stamp printing uses a metal engraved plate that is heated and transfers an image from the hot stamp printing foil directly to the IV container under pressure. Hot stamp printing is not capable of printing consistent solid blocks, such as a white background for bar codes. When trying to print a solid background, "pick away" occurs, leaving void areas that can make bar codes difficult to read.

Printing of lot number and expiration date also requires a printing process that can print variable information at the time of manufacturing. Metal hot stamp dies typically cannot be designed and manufactured in time to have the lot number and expiration date information ready at production time. The process of creating a hot-stamp printing plate and installing it on a manufacturing line takes time and limits the ability of manufacturers to include accurate lot number and expiration date, which the United States Food and Drug Administration (FDA) and health-care advocates recognize as critical elements to increasing patient safety.

Finally, because of the many technical challenges faced in the manufacturing process that degrade the resolution of hot-stamp bar coding on IV bags, scanners not only have difficulty reading the bar codes directly off the surface of the flexible IV bags, they also find it extremely difficult to read the bar code when the IV bag is enclosed in a translucent protective overwrap. However, the translucent protective overwrap extends the shelf life of the drug or solution enclosed in the flexible IV bag. Once the overwrap is removed to allow for scanning, the shelf life is reduced from months or even years to no more than 30 days.

#### **Approach to bar code problem**

Baxter approached the problem with four main goals in mind: print a high-resolution bar code that would feature increased scanning readability; print a bar code that could be scanned using current technology, including the installed base of readers currently in use in many hospitals; print a bar code that could be scanned through the translucent protective overwrap; and develop a system of printing the bar code on the flexible IV bags that would allow for easy inclusion of variable information such as lot number and expiration dating without relying on hot stamp plates

Baxter could have very easily and at a much lower cost simply printed a colored bar code on its clear IV bag using a hot-stamp printing process. However, Baxter chose not to go this route because it did not meet the health care system needs.

Scanners cannot consistently read a dark colored bar code on a clear IV container. The only way a scanner can consistently read a dark colored bar code on a clear bag is to place the bag over a white background such as a white piece of paper. Even then, the solution in the IV bag actually can distort the laser light that is meant to penetrate the bag to be reflected by the white piece of paper and back to the scanner.

#### **The solution**

With the goal to develop and implement a consistently readable bar coding technology that would provide the flexibility to include variable information, Baxter set out to develop a bar coding technology that the health care system needs and wants. Baxter wanted a high-resolution print quality that would allow for bar codes to be scanned quickly and easily. Baxter also wanted to meet the industry demand to incorporate the lot number and expiration date into the bar code to enhance patient safety. Additionally, Baxter wanted a technology and a standard that recognizes the global nature of health care.

The result was the development of Baxter's new patent-pending ENLIGHTENED<sup>HRBC</sup> bar code technology. ENLIGHTENED<sup>HRBC</sup> is a high-resolution printing technology that uses computer-generated images that can be programmed at the time of

manufacturing to include the lot number and expiration date information. This is a critical breakthrough that makes Baxter's bar coding technology cost-effective and viable for the millions of flexible IV bags Baxter manufactures each year.

In addition, Baxter is incorporating the UCC/EAN bar coding standard across its Medication Delivery product line. UCC/EAN is a global standard for identifying products. Given the variety of products that Baxter's customers manage within their facilities, and often from a wide variety of manufacturers, Baxter feels that a global system that crosses multiple industries is the best choice for its bar coding standard. The National Drug Code (NDC) number is included within the UCC/EAN bar code.

### **The benefits of bar coding medical products**

Bar coding of pharmaceuticals can play an important role in making sure that the patient receives the five -rights of medication management -- right patient, right medication, right dose, right time and right route of administration. Data from the VA Medical Center in Topeka, Kansas, and other medical centers where point of care systems using bar codes have been implemented, support that the bar coded products used in combination with medication management systems at the point of care can significantly reduce the frequency of medication errors and enhance patient care (8) (9) . In a multi-year study conducted by the VA, researchers found an astounding 86.2 percent reduction in medication errors (10). This included a 75 percent improvement in errors caused by the wrong medication being administered to a patient, 93 percent improvement in errors caused by the incorrect dose being administered to a patient, and a 70 percent improvement in errors caused when medications scheduled for administration were not given (11).

Bar coding is one of the enabling technologies that helps promote improved patient safety and reduced supply chain management costs within the health care system. The benefits of bar coding are important because automated systems can outperform humans in tasks requiring repetition, tiresome movement, intense concentration, immense memory retention and meticulous record keeping. Given the labor shortages facing nursing and pharmacy staffs in the United States, automation of routine tasks and implementation of systems to improve work flow will free time for clinicians to focus on patient care and medication management.

Bar code labeling of drugs and other FDA-regulated products can also facilitate product tracking for billing and reimbursement purposes and improve supply chain efficiency.

### **Conclusion**

At first glance, one would think that the application of bar codes to medical products

would be easy. However, medical bar coding is more complex than retail bar coding because of the unique nature of medical products and devices. The small size of many items and sterile manufacturing processes make bar coding small tablets, flexible IV containers and other medical products difficult. As we apply a bar coding technology to the industry, we need to implement a technology that is consistently easy to scan and that provides value to the industry. One key value is to add lot number and expiration date within the bar code. Inclusion of the lot number and expiration date in the bar code requires that the bar code be added during the manufacturing process, adding another step and costs to the process.

Medical bar codes do not by themselves improve the quality of medical care or reduce the potential of medication errors. However, when used in conjunction with a comprehensive medication management system, auto-identification systems such as bar codes can reduce the risk of medication errors and enhance patient care. In addition, the inclusion of bar codes that feature lot number and expiration dates on FDA-regulated products can further help improve patient safety, supply chain efficiency, and facilitate the accurate capture of product usage information for billing and reimbursement purposes.

- (1) Institute of Medicine. To Err is Human: Building a Safer Health System. Washington D.C.: National Academy Press; 1999.
- (2) FDA Is Urged to Hasten Efforts To Require Bar Codes on Drugs. The Wall Street Journal, July 29, 2002
- (3) FDA Public Hearing, Bar Coding: A Regulatory Initiative. July 26, 2002. p 16-17
- (4) Good Samaritan Hospital,
- (5) FDA Public Hearing, Bar Coding: A Regulatory Initiative. July 26, 2002. p 70
- (6) RSS is a registered trademark of the Uniform Code Council.
- (7) Composite Symbology is a registered trademark of the Uniform Code Council.
- (8) Veterans Affairs Bar-Code Scanning System Reduces Medication Errors. American Journal of Health System Pharmacists. Volume 59. April 1, 2002.
- (9) FDA Public Hearing, Bar Coding: A Regulatory Initiative. July 26, 2002. p 10
- (10) Veterans Affairs Bar-Code Scanning System Reduces Medication Errors. American Journal of Health System Pharmacists. Volume 59. April 1, 2002.
- (11) Veterans Affairs Bar-Code Scanning System Reduces Medication Errors. American Journal of Health System Pharmacists. Volume 59. April 1, 2002.

---

[news home](#) | releases: [2002](#) | [2001](#) | [2000](#) | [1999](#) | [1997 & 1998](#)

[home](#) | [patients](#) | [health-care professionals](#) | [customers](#) | [corporate info](#) | [careers @ baxter](#) | [find](#) | [news](#) | [feedback](#)

---

© [Copyright 1995-2002 Baxter Healthcare Corporation. All rights reserved.](#)  
[Legal Disclaimers](#) | [Privacy](#)