Bar Code Label Requirements for Human Drug Products

Submitted by Bruce R. Wray, Director of Marketing, Computype, Inc.,
Leading supplier of bar code labels, scanners, systems & software
Computype, Inc., 2285 West County Road C, St. Paul, MN, 55113; 651/633-0633; 800/328-0852; www.computype.com

Introduction

The case for bar code use in healthcare is compelling, and its broad implementation long overdue. As Laura Landro recently wrote in *The Wall Street Journal:* "For years, doctors and hospitals have lagged behind other industries in joining the information technology club--and it didn't look like they'd ever sign up. Because of the unusual payment structure of the healthcare industry, providers have never had many incentives to actually improve the quality of their product or install clinical information systems that would let them manage patient care better. In addition, health care tends to be local, and not subject to the competitive forces that have forced quality improvement elsewhere--such as the auto industry after Japanese carmakers arrived. Don Berwick, founder of the non-profit Institute for Healthcare Improvement, once famously said, 'So far, healthcare has no Toyota.'"

Whether or not Toyota has finally arrived in healthcare is now irrelevant—other market forces have combined to fuel an interest in information technology along with the benefits automated data collection via bar codes can provide. These market forces include:

- Proof it works
- Concerns about terrorism
- New federal rules
- Safety issues
- A powerful watchdog

Proof it works. Significant studies have proven the pay-off in automation. "There is a clear linkage now between technology and better patient outcomes" according to the president of Health Information and Management Systems Society.
Concerns about terrorism. A national information network to detect bio-terrorism attacks and disease outbreaks is at the top of the government's agenda for the first time since the idea first took root a decade ago. The Office for Public Health Preparedness is seeking more than $1 billion for programs like the CDCs Health Alert Network and a National Electronic Disease Surveillance System.
New Federal rules. Starting next year the Health Insurance Portability and Accountability Act (HIPAA) takes effect which mandates a standardized method for insurance companies and doctors to exchange financial and administrative information electronically.
Safety issues. The oft-sited Institute of Medicine study (1999) served as a wake-up call to health care—between 40,000 and 98,000 deaths per year in the US attributable to medical errors, costing up to $177 billion per year. By the FDA's own estimates, 28% - 95% of those errors could have been prevented, and 30% - 50% were caused by devices they regulate.
A powerful watchdog. The Leapfrog Group is a coalition of more than 100 public companies and private organizations that provide health-care benefits to more than 31 million enrollees. They're using their purchasing clout to prod hospitals to improve safety and patient care.

Leapfrog members spend about $53 billion annually on their employees' health care; they run a web-site that rates how well hospitals meet its standards--and to get a good grade, hospitals will have to make big IT investments.

For these reasons, healthcare is finally arriving at the automated data collection party. Let us hope it is not too late to catch up.

Bar Codes in Blood Banks

The modern blood bank could scarcely function without bar codes. From blood collection to manufacturing to distribution, the role played by automated data collection via bar code scanning is critical.

The international blood bank community was one of the first groups to standardize on the use of bar code technology. In 1974, the Committee for Commonality in Blood Banking Automation (CCBBA) was formed through a joint effort of the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers, now known as Americas Blood Centers (ABC). Through their efforts towards commonality, they pioneered the use of bar codes in blood identification. In the mid 1980s, some of those same organizations issued *Guidelines for the Uniform Labeling of Blood and Blood Components*, the bar code standard still in use today.

Why Bar Codes?

The use of bar codes in blood banks has proliferated because it is both fast and accurate (see table below). While it is not the only method of data collection available, it is superior to most because there is no trade-off between speed and accuracy. Equally important is its ease of use. Unlike Optical Character Recognition technology (OCR), in which it is critical to carefully align the reading head with a row of small printed characters, bar codes are vertically redundant. That is, the message at the top of the bars is the same as at the bottom, so a precise straight-line scan is not necessary for successful decoding. This might seem an obvious characteristic of bar codes, but its advantage became clear during a length study done by the Department of Defense in the early 1980s comparing the time and costs associated with data collection via key-entry, OCR, and bar codes. Add to that the dramatic performance increases and cost decreases of microprocessors, and the rationale for bar code technology becomes compelling—fast, accurate, easy-to-use, and inexpensive.

Comparison of Manual Data Entry vs. Bar Code Data Entry

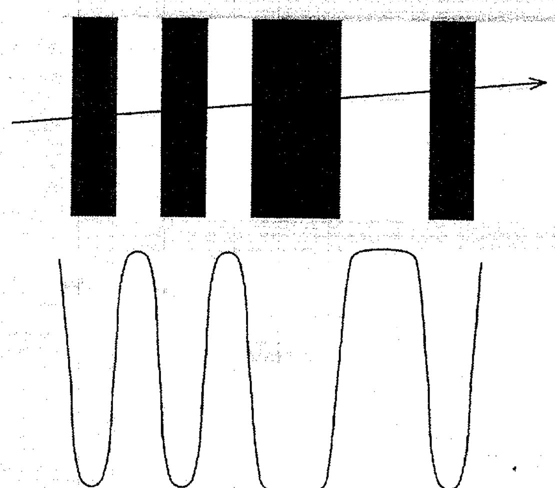
(12-character alphanumeric message)	**MANUAL ENTRY**	**BAR CODE SCANNING**
TIME REQUIRED	4 to 6 seconds	1 to 2 seconds
ACCURACY	1 error/300 characters	1 error/10 million characters

How well has their standard bar code symbology—Codabar—served the blood bank community? In the early 1990s, a major blood bank on the East Coast did an extensive study of their use of bar code scanning technology over a two-year period. The overall substitution error rate (the likelihood that incorrect information is entered into the system via bar code scanning) was 0.00007%. The new Code 128-based symbology being implemented by the international blood bank community also contains a check character, while Codabar does not. Check characters are designed to reduce the chance of a substitution error.

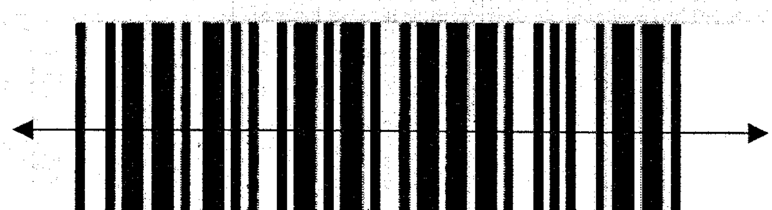
How Do Bar Codes Work?

While most people see bar codes every day, fewer understand the technology. Bar code scanning is based on a simple principle—Light is reflected in different amounts by different colored surfaces. To decode the information in a bar code, a small spot of light is passed over the bars and spaces via a scanning device. This bar code scanner can be a hand-held wand, a fixed beam device, or a moving beam device. The bar code will reflect the spot of light back into the scanner in varying amounts. That is, the dark bars of the bar code will absorb light, while the white spaces will reflect light. These differences in reflectivity are translated into electrical signals by a light detector inside the scanner. The signals are converted into binary ones and zeros; these are used in various combinations to stand for specific numbers and letters.

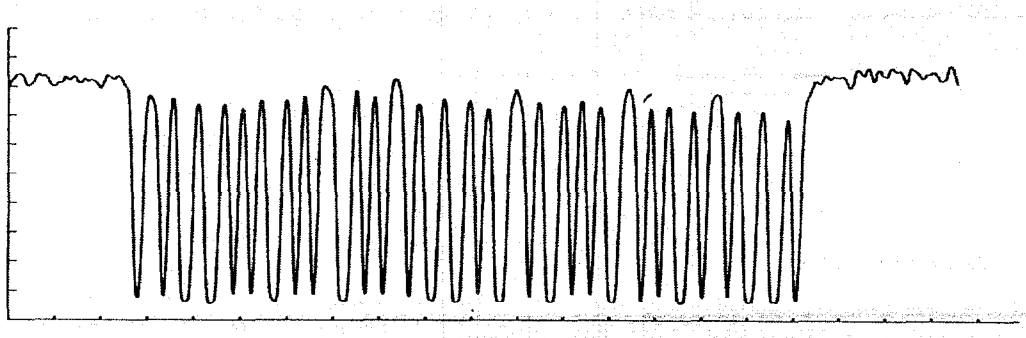
Scanning A Single Bar Code Character
And The Corresponding Analog Signal



Scanning an Entire Symbol



What the Scanner "Sees"



The New Bar Code Standard in Blood Banks

Recent standardization efforts within the international blood bank community have led toward adoption of a new symbology standard—Code 128. Code 128 was recommended for use within the international blood bank community to address several concerns regarding the current standard, Codabar:

- Susceptibility to substitution errors, and the lack of space to incorporate a check character to reduce the likelihood of such an error;
- Consolidation of testing facilities increasing the possibility of duplicate numbers being received within a single facility because of limitations of the seven-digit field;
- Product code structure had not been updated to reflect the proliferation of new blood products.

The selection of Code 128 was made unanimously because a number of important features made it the best choice for the needs of the blood bank community:

- <u>Fully alphanumeric</u>—Code 128 has the capability of encoding ten digits, (0-9), all upper- and lower-case alphabetic characters (A-Z, a-z), and more than thirty ASCII control characters, such as Carriage Return, Line Feed, Start Transmission, End Transmission, etc.
- <u>Widely supported</u>—Created in 1981, Code 128 was quickly accepted by the Automatic Identification Manufacturers, Inc. (AIM) as a Uniform Symbology Specification. All major scanner (bar code reader) companies support Code 128 in their decoders; it is in the public domain and is probably one of the three most popular symbologies based in the world today.
- <u>Continuous/High density code</u>—Continuous codes make use of every bar and space in the symbol. No space is wasted separating adjacent characters. In addition, Code 128 has a special numeric-only subset of particular usefulness when encoding a long string of numeric data. Subset C of Code 128 contains all numeric pairs from "00" to "99". Each character in this subset translates to two numbers, so twice as much data is encoded in the space that would otherwise be occupied by a single non-numeric character. In the figure below, note that both Code 128 symbols encode eight data characters; the one on the left is shorter because it is all

numeric and utilizes Code 128 Subset C, one of the most space-efficient linear symbologies ever developed.

Density Differences

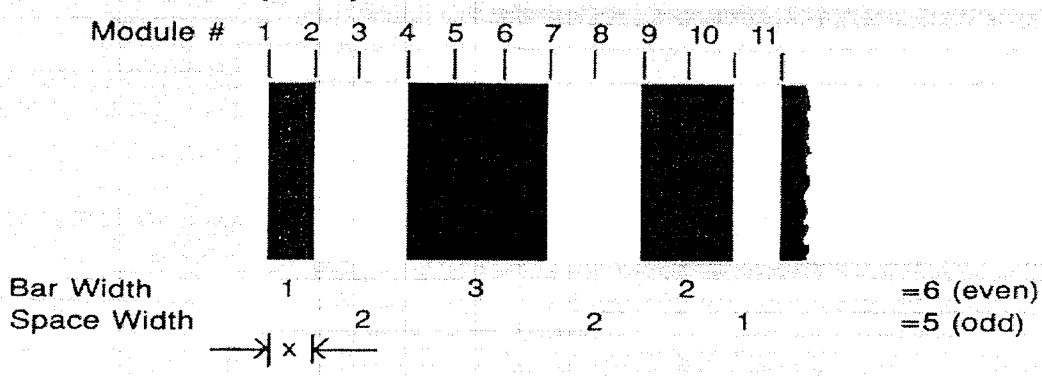
12345678

Subset C (above); Subset B (below)

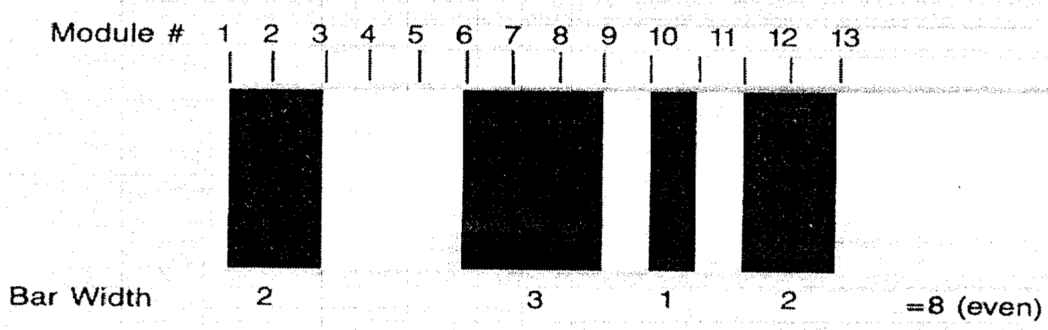
A1B2C3D4

- Flexibility—Code 128 provides unique flexibility by enabling the user to switch from one subset to another even within the same symbol. For example, in the *ISBT 128* Donation Identification Number, the first two characters of the bar code are in Subset B because they are not available in any other subset. Then, a special character is inserted that switches to double-density Subset C for the remainder of the entirely numeric message.
- Data security—This was a critical concern for blood banking. Each character within each Code 128 symbol has three separate self-checking features, as indicated below. (A bar code symbology is termed "self-checking" if a single printing defect will not cause a character to be transposed into another valid character in the same symbology.) In addition to three self-checks per character, every Code 128 message requires a modulus 103 check character, designed to ensure that the entire message has been scanned correctly. This weighted check digit routine is capable of detecting both errors of transcription and errors of transposition.

Character 1 (one)



STOP Character



- Ease of printing—Although it has served the blood banking community well for over a quarter of a century, Traditional Codabar is not an easy symbology to print because of its 18 different element widths and therefore the need for high resolution printing processes. Code 128, with only four element widths, is easy to print using all common bar code printing technologies.

Automated instruments within the blood bank typically use moving-beam laser scanners built in to the mechanism of the instrument. Orientation of the symbol with respect to the scanner is determined by the rack or carousel employed. These scanners typically require a minimum number of successive identical decodes before declaring a valid scan and transmitting the data.

In the mid-1980s, bar code scanners became available that were "wedge" devices; that is, they were wedged between keyboards and PCs and emulated keyboard data entry. That allowed blood bankers to use their current software applications that continued to function exactly as before, but with the added benefit of fast and error-free data entry. Wedge readers are common in blood banks, and allow either key-entry or bar code data entry simultaneously.

What's Next In Healthcare Auto ID?

Linear bar codes are not the only method of automated data collection. While they are clearly superior, as was pointed out earlier, to Optical Character Recognition and manual data entry, linear bar codes have inherent limitations that other, newer technologies do not have. Technology is changing at an ever-increasing rate, but the summary that follows will highlight most of the major identification technologies that may replace or enhance the scanning of a simple bar code in healthcare.

Stacked bar codes are a series of linear bar codes stacked directly on top of one another that form one continuous message. An example of a stacked code is shown below.

Advantages: Higher capacity than linear codes, read by conventional laser scanners, error detection/correction in most symbologies, printed similar to linear
Disadvantage: Read-only

Code 16K Symbol

Matrix codes are made up of a block of cells that are filled or unfilled to represent binary data, generally arranged on a square grid. Examples of matrix codes are shown below.

Advantages: Large data capacity, well-founded optical technology, error detection/correction, printed similar to linear

Disadvantages: Must be ready by image processors (2-D array of CCD sensors); read-only

Data Matrix Symbol

PDF417 Symbol

What are the relative information encodation capabilities of the multi-row and 2-D symbologies? The graphic below indicates that for short message lengths, all three of the original multi-row symbologies have similar sizes, but the "micro" version of PDF417 is considerably smaller. Each symbol encodes the same 20-character message and uses the same "X" dimension (narrow element width).

TESTING 12345 ABCDEF

CODE 16K

TESTING 12345 ABCDEF

CODE 49

TESTING 12345 ABCDEF

PDF417

MicroPDF417

Here is a comparison of three symbologies encoding the same eleven data characters using the same "X" dimension. It is clear that the 2-D matrix symbology (Code One in this example) occupies much less label space and is therefore more efficient.

ABCDEFGHIJK

CODE 39

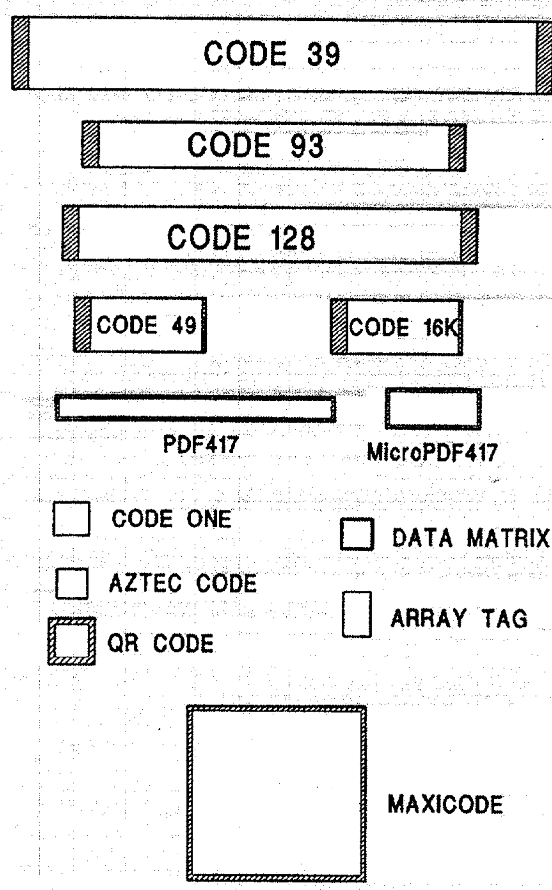
ABCDEFGHIJK

CODE 49

ABCDEFGHIJK

CODE ONE

Using a 20-character message with a 10 mil "X" dimension (0.010"), the outlines below indicate the relative size of space required to by each symbology. The cross-hatched areas represent the minimum required quiet zones (margin around the symbol).



What about scanning these new symbologies? The chart below summarizes the scanning equipment required to successfully read each type.

	Symbology Type		
Scanner Type	**Linear**	**2-D Stacked**	**2-D Matrix**
Wands	X		
CCD Scanner	X	X	
Handheld laser	X	X	
Handheld rastering laser	X	X	
Fixed-Mount laser (single scan line)	X	X	
Fixed-Mount laser (multiple scan lines)	X	X	
Image-Based scanner	X	X	X

Representative list prices of scanning hardware as of July, 2002 is presented below based on a quantity of one.

Pen/Wand Scanner:	$240
CCD Scanner	$420
Linear Imager	$570
Laser	$890
2-D Imager	$985

Contact memory devices are data carriers typically packaged similar to button-type batteries; as a result, this technology is sometimes referred to as button memory.

Advantages: Read-write, high capacity, relatively low-cost tags, programming, and readers
Disadvantages: Direct contact required, limited use (about 40 million worldwide)

Magnetic stripe technology is far from new. It is used on credit and ATM cards, as well as many hotel room "keys" and in other access control applications.

Advantages: Widely-used, low-cost media, fairly durable, read-write
Disadvantages: Contact-read only, susceptible to fraud, limited data capacity

Smart cards are true portable data files. They are essentially a "chip in a card," where data is transferred electronically through a set of contacts.

Advantages: Read-write and processing capabilities, high data capacity, more secure than magnetic stripe through selective access and encryption
Disadvantage: Requires contact or close proximity

Radio Frequency Identification Of all the "exotic" technologies for automatic identification in healthcare, RFID is perhaps the most powerful and most likely to be implemented in the near future. RFID systems use radio transmissions to communicate with an object having an attached transponder, or tag. Data is returned by radio to a reader linked to a host. "Smart labels" have an RFID integrated circuit embedded in them which can be stored, read, or updated via radio signals.

Advantages: Do not require a battery (passive RFID), unlimited operating life, excellent environmental endurance, working distance from contact to 3+ feet, line-of-sight not required, reader can differentiate among many tags simultaneously, read/append or read/rewrite on the fly, on-demand printers available for smart label printing and encoding
Disadvantage: Cost per tag remains high, around $0.40 to $1.00 each, although this is expected to decrease as usage increases.

While many of these newer technologies offer great promise for use within the blood bank, the standard against which they all must be measured is the bar code—the easiest and most cost-effective method for automatic identification available today. That which is efficient and effective is also safe—the health care community can and will be well served by bar codes.

Recommendations

1. The FDA should require the use of machine-readable symbols on all human drug and biologic products. Eye-readable representation of significant information should always accompany the machine-readable symbol(s).
2. Rather than require a specific bar code symbology (language), the FDA should mandate that an agreed-upon data structure be encoded for machine reading. Where existing standards are available, such as *ISBT 128*, their use should be required
3. Guidelines should be provided to each stakeholder industry group by the FDA which outline the minimum information content of their symbol(s), and the timeline for implementation.
4. An Auto ID Coordinating Council should be appointed to help resolve implementation issues. The AIDCC would be made up of volunteers from the disciplines involved in the new requirements, bar code suppliers, and the FDA. It would be charged with ensuring minimum information requirements are met, that the best technology available is used, and that costs to individual institutions and firms is minimized.

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For additional information regarding:

ISBT 128
ICCBBA, Inc.
204 St. Charles Way
Unit 179E
York, PA 17402
To order ICCBBA documents: 717/845-4790
www.iccbba.com

American Association of Blood Banks (AABB)
8101 Glenbrook Road
Bethesda, MD 20814
To order AABB documents: www.aabb.org

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike
Rockville, MD 20852-1800
To order FDA documents: 800/835-4709

Bar Code Print Quality Guideline (X3.182-1990)
American National Standards Institute
11 West 42nd Street
New York, NY 10036
To order ANSI documents: 212/642-4900

Uniform Symbology Specifications
AIM-USA
(Automatic Identification Manufacturers)
634 Alpha Drive
Pittsburgh, PA 15238
To order AIM documents: 412/963-8588
www.aimglobal.org

Health Industry Standards (non blood banks)
HIBCC
(Health Industry Business Communications Council)
5110 North 40th Street
Phoenix, AZ 85018
To order HIBCC documents: 602/381-1091