Technology White Paper

Automated Data Collection Improves Safety and Efficiency in Clinical Applications

An In-Depth Evaluation of Bar Codes and Value-Added Bar Code Reading Subsystems for Lab Instruments

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This white paper presents an in-depth evaluation of bar codes and value-added bar code reading subsystems for lab instruments. The automation of data collection through bar code technology improves patient care and clinic efficiency by ensuring the accuracy and expedited availability of clinical data. The topics addressed in this paper include:

- *Clinical Bar Coding Applications*
- *Bar Code Symbologies*
- *Laser Scanner Technology*
- *Application Challenges*
- *Good Design Flexibility for Embedded Applications*
- *Other Embedded Design Considerations*

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Since the 1999 publication of a landmark report by the Institute of Medicine on safety deficiencies in the delivery of healthcare, many initiatives have been set into motion to improve patient care and prevent the 770,000 medication errors estimated by the report to take place each year in U.S. hospitals.[1] The increasing use of bar code labels has been central to this corrective effort.

Physicians rely heavily on laboratory test results to make informed decisions regarding the care a patient receives. Bar code readers embedded in analytical instruments can help laboratories ensure that their test results are as accurate as possible by automating the data entry process. By eliminating manual entry, bar code readers take human errors out of the equation. Data integrity is ensured when patient samples and reagents are scanned.

Bar code readers help instrument designers streamline the data capture process. Also, as explained in this article, their design can further reduce the occasions for data entry errors and misreadings.

Figure 1. *Miniature megapixel imagers quickly read multiple 1D and 2D codes in a single image capture for highly efficient data acquisition.*

Clinical Bar Coding Applications

Bar codes are used in clinical analysis for specimen and reagent identification. A contained specimen—that is, a clinical sample taken from patient—is usually bar coded with a unique identifier known as specimen ID. This allows the laboratory information system (LIS) to identify the specimen automatically and associate it with a particular patient in the database (see Figure 1).

When a specimen is placed on an analyzer, the bar code reader or readers embedded in the analyzer acquire and decode the specimen ID. This ID is then sent to the LIS, which actually receives two pieces of information—the specimen ID and the analyzer ID. Based on this information, the LIS queries its database for requests for tests of the specimen that are to be performed on that analyzer. Test requests that match the specimen and analyzer identifiers are downloaded to the analyzer. The instrument now has the information necessary to undertake clinical analysis of the specimen.

When the analysis is completed, the results are sent to the LIS for posting to the database. The process allows physicians to access their patients' test results without having to wait for paper reports to come from the laboratory.

The second common clinical bar code application is the automated handling of the information related to consumables, such as reagents. The automated identification of non-test-specific bulk reagents allows for the creation of a more complete record associated with each test result. But more important is the tracking of test-specific reagents. Most reagent packages contain a linear bar code that identifies the type of test for which the reagent is suitable and a pack serial number or other unique identifier. While reagent manufacturers go to great lengths to ensure that all lots, or batches, of a reagent are as similar as possible, variations in raw materials nevertheless prevent lots from being absolutely identical. As a result, it is common for analyzers to have to be given lot-specific values for a number of parameters. This kind of information is often supplied by means of computer disks, bar coded cards, or other forms of media separate from reagent container itself.

Bar Code Symbologies

The bar code symbologies in use today fall into two categories: 1D linear and 2D stacked linear or matrix. Both 1D and 2D codes are employed in clinical applications.

Linear bar codes are typically used for sample identification. The traditional bar code can best be described as a machine-readable symbol with the appearance of a series of parallel dark bars and light spaces. The data in the symbol are encoded via predetermined-width patterns. The format of these patterns is defined by the particular symbology selected. Since only the widths of the bars and spaces are important in decoding a linear bar code, single-row bar codes are considered one-dimensional codes (see Figure 2).

The data characters of linear bar code like that shown in the figure contain the encoded information. Preceding the first bar and following the last bar in the code is a space called the quiet zone. For a laser scanner to read the code reliably, the quiet zone must be minimum of 10 times the width of the narrow bar, which is designated in example depicted, and must be kept free of print or marks of any kind. The check digit, for which the error-correction code word in a 2D symbol is a counterpart, provides a degree of data security in a linear symbology that employs the device. Bar height simply provides redundancy for a linear bar code. The narrow bar width alluded to above is nominal dimension of the smallest bars and spaces in a bar code symbol and determines the size scale of the bar code.

Two-dimensional bar codes are most often used for reagent identification. Two-dimensional codes can be grouped into two categories: stacked linear codes and matrix codes. Stacked codes, such as PDF417, are rows of width-modulated bar codes stacked exactly vertically. Each row is the same length and resembles a single-line bar code (see Figure 3). PDF417, the stacked code illustrated in the figure, features a code start and code-stop pattern and left and right row indicators, which establish orientation. The center section contains the data. PDF417 contains three different row encoding schemes that repeat every three rows. For example, row 1, row 4, row 7, and so on, share the same bar pattern for the alphanumeric character A.

Matrix codes are another type of two-dimensional code. They are composed of a two-dimensional pattern of light and dark elements, or data cells that are arranged into the shape of a square, circle, or polygon (see Figure 4). Data Matrix, the most popular

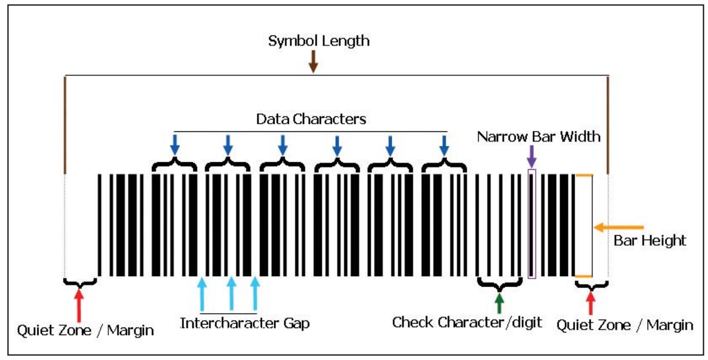

Figure 2: *A single-row linear (1D) bar code.*

matrix symbology, resembles a checkerboard. With reference to the figure, a matrix code consists of a data region that contains the data and error-correction code words, which is situated within a surrounding finder and clocking pattern, the whole bordered by a quiet zone.

Rows and columns of the symbol are made up of square cells called elements that each encodes one bit of binary data, a zero or a one. The outermost rows and columns of the symbol comprise one solid row and one solid column that together constitute the structure finder pattern, and one row and one column of alternating dark and light elements that make the clocking pattern. The finder pattern determines symbol orientation, and the clocking pattern determines the size of the symbol in terms of the number of rows and columns in it. The quiet zone on each side of the symbol must be a minimum of one element in width according to the Automatic Identification Manufacturers (AIM) specification.

Matrix codes such as Data Matrix have been rapidly gaining in popularity for use in identifying reagents. One reason for this is the nearly infinite scalability of Data Matrix, which provides large data capacity within a very small footprint (see Figure 5). Data Matrix can encode as many as 3116 purely numeric characters and up to 2335 alphanumeric characters.

Also, Data Matrix offers the Reed-Solomon method of error correction, which makes it highly resistant to misreadings due to symbol damage. With Reed-Solomon error correction, as much as 50% of the symbol can be damaged, torn, or distorted by condensation without loss of readability. The error-correction function identifies two types of errors: rejection errors, called erasures, and substitution errors, conventionally called, simply, errors. An erasure is

Figure 3: *PDF417, an example of a 2D stacked bar code, is composed of rows of width modulated bar codes stacked on top of the other.*

a missing, unscanned, or undecodable symbol character whose position is known but now its value. An error is a misread or mis-located symbol character. In this case, both the position and the value of the character are unknown.

Since matrix codes are two-dimensional, they must be read using imaging technology. Stacked codes and linear codes can both be read by laser scanners; however, orientation of the code in relation to the laser beam is of key importance.

Laser Scanner Technology

The most common type of bar code scanner embedded in clinical instruments today is one based on laser technology and is used for decoding—that is, reading—1D bar codes.

As the laser spot, which moves so fast that it appears to the eye as a line, passes over the dark and light elements of the code, a photo detector in the scanner measures the amount of light reflected back by each element (see Figure 6). The photo detector converts the reflected light energy into electrical energy, which is then transformed through signal processing from an analog to a digital signal. The digital signal is decoded according to the formulas of the symbology (algorithms). Once decoded, either the data can be directly output to the LIS or the bar code scanner can perform logical tasks using the data.[2]

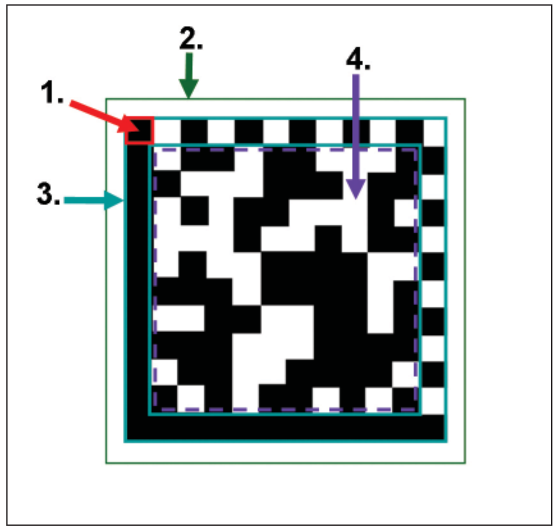

Figure 4:
The matrix type of 2D bar code. Highlighted are an element (1), the quiet zone (2), the structure finder and clocking patterns (3), and the interior data region (4).

Symbol Size *Row x Column*	**Data Capacity** *Numeric*	*Alphanumeric*	**5 mil Examples**	**7.5 mil Examples**	**10 mil Examples**	**15 mil Examples**
10 x 10	6	3	1.27 mm	1.90 mm	2.54 mm	3.81 mm
12 x 12	10	6	1.52 mm	2.29 mm	3.05 mm	4.57 mm
14 x 14	16	10	1.78 mm	2.67 mm	3.56 mm	5.33 mm
16 x 16	24	16	2.03 mm	3.05 mm	4.06 mm	6.10 mm
18 x 18	36	25	2.29 mm	3.43 mm	4.57 mm	6.87 mm
20 x 20	44	31	2.54 mm	3.81 mm	5.08 mm	7.62 mm
22 x 22	60	43	2.79 mm	4.19 mm	5.59 mm	8.38 mm
24 x 24	72	52	3.05 mm	4.57 mm	6.10 mm	9.14 mm
26 x 26	88	64	3.30 mm	4.95 mm	6.60 mm	9.91 mm
32 x 32	124	91	4.06 mm	6.10 mm	8.13 mm	12.19 mm
36 x 36	172	127	4.57 mm	6.86 mm	9.14 mm	13.72 mm
40 x 40	228	169	5.08 mm	7.62 mm	10.16 mm	15.24 mm
44 x 44	288	214	5.59 mm	8.38 mm	11.18 mm	16.76 mm

Figure 5:
Data Matix is infinitely scalable. The chart shows Data Matrix ECC 200 symbology specifications commonly used for life science environments.

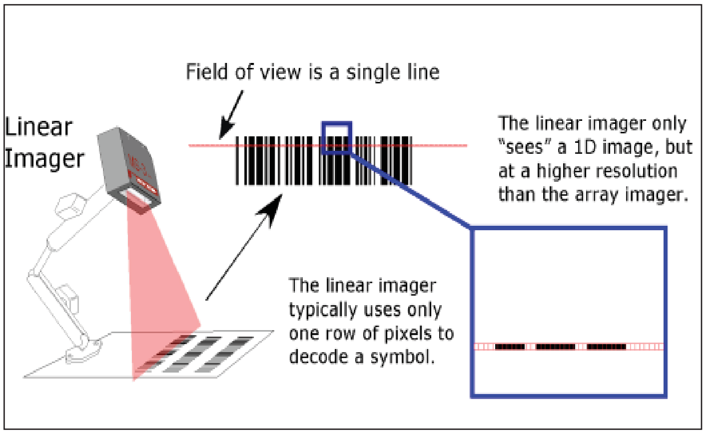

Figure 6: *The linear imager typically uses only one row of pixels to decode a bar code symbol. It perceives a 1D image, but at a higher resolution than the array imager.*

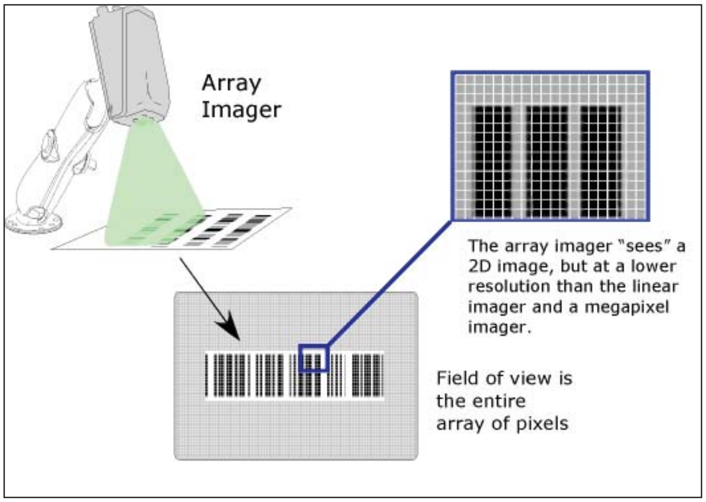

Figure 7: *The array imager views the entire array of pixels. It perceives a 2D image, but at a lower resolution than the linear image and megapixel imager.*

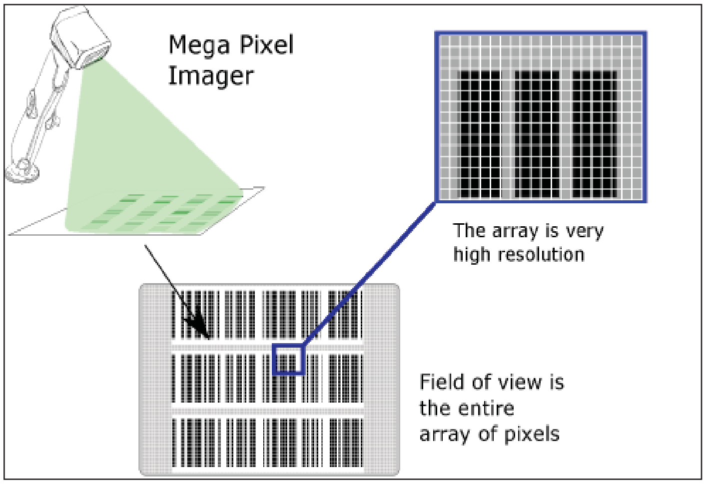

Figure 8: *Megapixel imagers provide designers with both high resolution and large field of view, enabling bar code readers to read multiple high density codes in a single image capture.*

Linear imagers are similar to laser scanners in that their field of view is only one pixel tall and many pixels wide (see Figure 7). Since they process across a single line, they cannot decode two-dimensional images.

Reading a 2D symbol, such as a Data Matrix, requires an array, or megapixel, imager. Such imagers use an array, or matrix, of gray-scale pixels to process the symbol (see Figure 8). They also typically use an embedded array of light emitting diodes (LEDs) to illuminate the image, instead of a single laser diode or a single row of LEDs. A charge-coupled device (CCD) or complementary metal oxide semiconductor (CMOS) sensor collects the photon energy reflected back from the object of interest and the converts that energy into an analog signal that is subsequently converted the digital gray-scale value for the central processing unit to process.[3]

In order for any linear bar code reader to perform properly, the laser line—or the linear field of view in the case of a linear imager—must be aligned perpendicularly to the bars and spaces of the code. The orientation of the bar code and the direction of its travel are very important to systems using a linear bar code reader. But since array imagers process images two-dimensionally, orientation of the code or symbol is not relevant. Also, imagers are generally much more forgiving of contrast and symbol damage. This is because they capture the entire symbol at one time rather than scanning it one line at a time.

Application Challenges

Bar coding systems have helped laboratories streamline their processes for many years. Studies have shown that, while one out of 300 manually keyed laboratory data entries results in an error, only one out of 3 million scanned entries (using a code 39 bar code) does.[4] Errors, however, do occur. The causes are chiefly poor bar code production or label orientation and environmental circumstances.

Poor Quality Bar Codes

The large majority of bar code reading errors are caused by poor quality bar codes or improper bar code orientation. One of the biggest bar coding challenges laboratories face is to be able to consistently generate bar code symbols of acceptable print quality that can also withstand the laboratory environment. Bar codes not meeting basic quality standards are commonly the cause of failed reads. Conditions such as poor contrast between the light and dark elements, inadequate or inconsistent resolution, quiet-zone violations, and label damage can all potentially cause readability problems. Many of these problems are easy to identify and fix.

Poor Bar Code Orientation

Another common cause of misreadings is the application of bar code labels in improper orientation. If the bar code is not aligned in such a way that the laser beam can pass through all of its bars and spaces, the scanner cannot read it. Orientation must be even more precise when a laser scanner is used to read a PDF417 stacked code (see Figure 9). (Orientation is significantly less of an issue for image-based bar code readers.)

Poor quality or improperly aligned bar codes may have to be completely relabeled or manually entered. This interrupts work flow and requires more handling by technicians, thus increasing the opportunity for misassociation and error. If human intervention is necessary for completion of the data entry process, then the opportunity for error increases dramatically.

Environmental Conditions

Additional potential causes of errors are variable ambient lighting and the glare from highly reflective label media. Since bar code readers, whether laser or imaging devices, use light to gather information, the environmental lighting must be factored into any application. Most readers contain software routines that can mitigate the risk of misreads caused by varying lighting conditions.

The use of these software routines often becomes a balancing act between speed and the ability to read bar code symbols that are printed significantly out of spec on the one hand, and the need for data integrity on the other. Scan speed is directly related to redundancy; the more looks a scanner gets at a bar code, the higher the chance of a good read. As a general rule, five looks at each bar code is recommended. Since most clinical applications are not high-speed applications to begin with, the scan rate of most laser scanners provides enough looks to provide sufficient redundancy.

Other environmental factors, such as condensation, also can distort the bar code, making it difficult for the reader to scan the code.

Good Design Flexibility for Embedded Applications

The scan envelope is the total dimensional space needed by a reader to decode a bar code at a specified distance (see Figure 10). This characteristic of a reader is especially important in space-constrained situations such as embedded applications. The challenge in decoding a bar code at close range is achieving a scan width, or field of view, long enough to span the entire length of the bar code. The scan envelope directly affects the space requirement for a particular reader that might be mounted within the instrument to read bar codes. The dimensions of the envelope are determined by the depth of the reader, the scan angle, and the distance between the reader and the symbol.

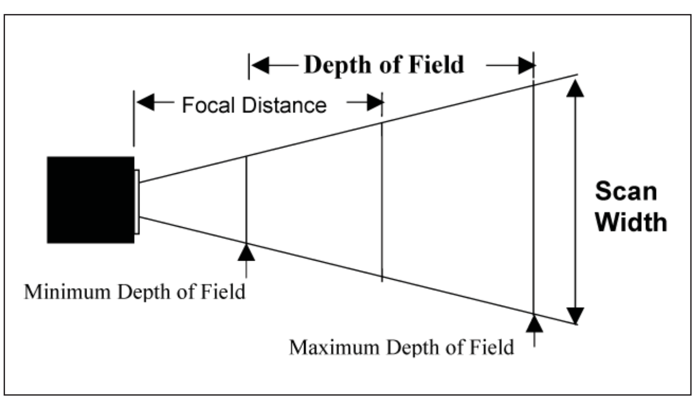

Figure 10. *The scanner depth, the scan angle, and the distance from the reader to the bar code collectively determine the scan envelope.*

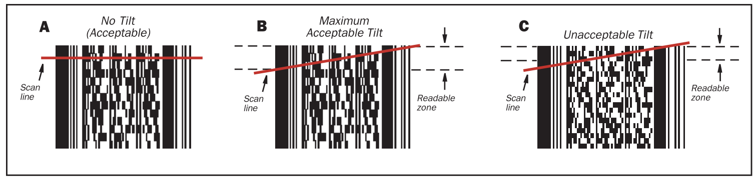

Figure 9: *Orientation is especially critical for reading PDF417 symbols with a laser scanner. Because the encoding scheme of a PDF417 label changes every three rows, a tilted laser beam may not cross more than three rows and still read the code. With symbols B and C in the illustration, the tilt is the same, but because symbol C has shorter row heights, its readable zone is correspondingly smaller.*

The depth of the bar code reader is easily determined by measuring the actual physical case of the reader. The angle of the scan is important because it directly determines the width of the scanner's laser beam. The scan distance is the separation between the front of the reader and the symbol that is required to achieve a successful read.

The mechanical envelope is the physical space required to accommodate the bar code reader in relation to the bar code. When embedding a laser scanner, how the scanner is oriented with respect to the bar code and the direction in which the bar coded container is traveling are important considerations.

Bar codes in motion may present themselves in either picket fence (horizontal symbol, vertical bars) or ladder (vertical symbol, horizontal bars) modes as defined by the direction of label travel. Picket fence orientation is generally recommended over ladder orientation because a scanner will have more time to scan the entire bar code as it passes through the scan width. Since imagers can read codes in any direction, readability does not depend on bar code orientation.

Other Embedded Design Considerations

Adding or replacing a laser scanner with an array or megapixel imager will not make an existing system obsolete. Array imaging technology is backward compatible with codes on legacy reagent packaging. For example, compact megapixel imagers are capable of reading traditional linear bar codes on samples, as well as the stacked PDF417 symbols and Data Matrix symbols on reagent cartridges. Their flexible depth of field and wide scan window make them well suited for applications that may involve multiple types of bar codes or symbols on a variety of packages, such as in central laboratories.

Perhaps more important, an array imager ensures that the bar coding system is forward compatible. A laboratory may not be using 2D codes today, but an embedded imager will provide it with that option in the future, extending the useful life of the laboratory instrument. Since these instruments can enjoy a very long life, a key economic consideration is that the embedded subsystems be able to accommodate future applications as well as current ones.

Imagers generally do not require as high a decode rate as laser scanners because they capture in two dimensions. In dynamic applications, decode rate is actually more important than the scan or image-capture rate because this determines how fast the scanner will be able to process the encoded data and send it to the host. For imagers, shutter rate and trigger timing are the most important considerations for speed. Decode rate comes into play only when throughput is discussed. Many compact megapixel imagers are not designed for high-speed applications, but are better suited for slow or stationary applications. The majority of analyzers use a stop-and-read system for reading bar codes, so this should not pose a serious limitation.

While imagers do not have the same high scan rates, they are able to read multiple stationary specimens simultaneously. This is not as fast as dynamic reading, but it is significantly faster than stop-and-read processing of single specimens.

Conclusion

Barcoding technology continues to advance and play an increasingly important role in any organization that wants to ensure the fast and accurate flow of information. Barcode readers in clinical and diagnostic instrumentation provide many substantial benefits in the laboratory. Manufacturers of such barcoding devices will continue to develop ways to optimize processes in clinical applications, reduce human error, and help health care professionals streamline the analytical process.

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