Docket No. 02N-0204

Bar Code Label Requirements
For Human Drug Products
Public Meeting (2002 July 26)

Perspective of a Systems Integrator & Supplier of Automatic Identification Reading and Printing Systems

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Introduction:

Having worked for a major pharmaceutical firm for six years applying this technology while helping pharmaceutical industry groups do the previous testing that developed existing standards, coupled with 27 years of bar code experience, 17 years of vision experience, 10 years of Datamatrix experience, and having spent the last 11 years running one of the premier systems integration providers to the pharmaceutical industry for this technology, we have a wider range of experience and understanding than most as regards the state of both the technologies being considered, and the ability of pharmaceutical and medical device companies to implement them.

Besides providing printing and reading solutions to the pharmaceutical manufacturer, we also deliver reading solutions to the end user market that has to read the codes produced by these manufacturers. We understand the true current level of implementation as well as how the manufacturer can and cannot produce the codes with the technologies that they currently have on the packaging line, and what the true costs of acquiring this capability are.

We also fully understand the relative technical merits of all the codes under consideration. It is disturbing that many see this need to implement an identification technology as one where only one symbology should be selected, when the reality is that there is no one size fits all. The systems to be selected will need the capability to print and read all of the appropriate symbologies. Perhaps most disturbing has been the distorted attack on Datamatrix, where costs to read and print it have been grossly exaggerated, and the technical advantages it has in many areas are minimized or ignored. We first installed this technology on Pharmaceutical packaging lines in 1994 and it greatly disturbs us to hear the many distortions and mistruths being spread as regards it's use and suitability.

Having installed several hundred vision systems, and over a thousand high speed bar code reading systems that have been validated, we understand the manufacturers needs and concerns. Our reading systems for the end users, and their need for accurate data capture is equally understood.

An Overview

The key issues are safety, compatibility, reliability, affordability, and product security.

Commonality of Data structures are a must.

The ability to fit the data on the drug or medical device is paramount.

The present 1 percent installed base cannot dictate the technology solution chosen.

The potentially lethality of the drug or device should be considered in determining whether NDC number encoding alone is sufficient. Increased danger mandates NDC number, lot number, and expiry date encoding.

The product cost and potential for counterfeiting may mandate the use of a supplemental four character alphanumeric serial number to identify to the individual unit level. The four character alphanumeric code could identify more than 1.6 million possibilities within a lot. On medical devices, the use of the sequential serial number could assure that all manufacturing steps are completed on a part when changing visuals are not apparent within the manufacturing processes. This is particularly true as pertains to processes such as heat treating and sterilization.

Code 128, RSS, and Datamatrix should all be acceptable symbologies. Much misinformation about the relative merits of RSS and Datamatrix has been cast about in the meetings discussing the needs for drug and medical device marking and identification. Both are needed, and both are required. Each has its strengths and weaknesses. NASA, the electronics, aerospace and automotive industries have all adapted Datamatrix for small part marking. RSS would be less costly to implement on the reading side, if only the RSS linear variants encoding only the NDC number were adapted today.

Hand held readers capable of reading all existing codes can be purchased today for less than $500 each. By this time next year, due to the development of CMOS Imagers on a chip using SOC (System On Chip) technology, the cost of imager based handheld readers will fall to the $200-$250 range. When choosing a reading technology, the end user should consider that unlike lasers, imagers have no moving parts to wear out.

Another important consideration, is the ability of the pharmaceutical manufacturer to print readable codes at high production rates. The ability to print data matrix codes at the fastest line speeds exist now. RSS can be printed on line at lower speeds. When variable on-line printing is to be accomplished, high speed thermal transfer or inkjet printing can meet requisite quality needs for data matrix. For matrix codes, Vision Systems that can both read and determine ANSI print grades at production speeds, now exist and can be run at speeds of over 2000 labels per minute.

Data matrix inspection systems are proven technology that was first installed on pharmaceutical lines in 1994. Virtually every vision system installed in the pharmaceutical industry over the last three years for human readable date and lot code inspection, is also datamatrix capable. The pharmaceutical user merely has to enable this capability on his existing systems. High-speed machine vision systems capable of reading RSS will start becoming available within 60 days. These will initially command a premium price. Installed costs for such systems will start at about $16,000. Costs for installed medium speed datamatrix systems start at about $8,000. It is anticipated that at some future date, the same systems will read will read all RSS variants at similar cost.

Code Comparison

NDC Number Encoded: 1234567890

Datamatrix	**.009**	
RSS-14 Limited	**.009**	
UCC-EAN 128	**.009**	 (01) 0 03 1234567890 6

NDC Number Encoded:1234567890
Plus Date and Lot Code 050530

Datamatrix	**.009**	
RSS-14 Limited Composite	**.009**	
UCC-EAN 128	**.009**	 (01) 0 03 1234567890(17)020530(10)1234567

NDC Number Encoded: 1234567890, Plus Date
020530, Lot Code 1234567 and 4 digit serial ID 1234

Datamatrix	**.009**	
RSS-14 Limited Composite	**.009**	
UCC-EAN 128	**.009**	 (01) 0 03 1234567890(17)020530(10)1234567(21)1234

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RSS-14 Limited	**.013**	
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NDC Number Encoded:1234567890
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Datamatrix	**.013**	
RSS-14 Limited Composite	**.013**	
UCC-EAN 128	**.013**	 (01) 0 03 1234567890(17)020530(10)1234567

NDC Number Encoded: 1234567890, Plus Date
020530, Lot Code 1234567 and 4 digit serial ID 1234

Datamatrix	**.013**	
RSS-14 Limited Composite	**.013**	
UCC-EAN 128	**.013**	 (01) 0 03 1234567890(17)020530(10)1234567(21)1234

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With currently installed technologies, datamatrix could be installed and made operational sooner by pharmaceutical companies. It would also allow the least label real estate to be used, allowing it to fit in where other symbologies will not. Even the most space efficient of the RSS variants, requires almost three times the area of similar print density datamatrix.

Some existing on-line fixed position laser reading systems will be upgradable to RSS, if the laser manufacturers have the incentives to do so.

A Plan for implementation that makes sense

Phase in lower lethality drugs first, using only NDC or UCC-EAN standards over the initial 18 months.

Use RSS and Datamatrix symbologies for higher lethality drugs to encode NDC, lot numbers, and expiry dates over a 36 month period.

For drugs of higher counterfeit potential, also add the 4 digit sequential serial number at the end.

This implementation schedule will allow the pharmaceutical manufacturers the time to invest, install, and validate the on-line printing and inspection systems required. The first phase would not require upgrades to on-line printing capability, since this data could be printed Off-Line. Manufacturers themselves should choose the 50 percent of their products that will fall into the first phase. Otherwise, implementation will be stalled, and deadlines extended, much as what happened with Component Verification during the 1990's.

The use of imager based readers will allow reading of all symbologies as well as the capturing of images. By capturing the physician's signatures, they would be more careful, more accountable, and the real world rate of transcription errors would be lowered.

Which Medical products should carry a bar code?

All prescription drugs, blood products, and medical devices that will be left within the body should be bar coded. All other products that have a likelihood of some patients having allergic reactions should also be bar coded. All implanted devices must be identified with a unique sequential serialized code.

What information should be contained within the bar code?

The bar code should identify the product. For a drug this means the NDC number. For most Rx products the code should also contain expiry date and lot code information, and for some a unique sequential serial number should be added at the end of the code, space permitting. By using the appropriate density data matrix code, there is no product that could not have all this information encoded despite it's size. A 4 character alphanumeric serial number at the end of the code would allow the identification of 1,679,616 unique items within a lot, making absolute traceability possible.

Which symbology should be selected?

Both the RSS and datamatrix codes can and should be utilized. It must be recognized that datamatrix will allow smaller codes to be created within the limited areas of labels and product identification, than is possible with RSS. It is also possible with datamatrix to create the extremely small codes that might be required on implantable devices. On many labels and packages, RSS-Limited or datamatrix could be used with equal effectiveness. Both RSS and datamatrix should be allowed. This requires the adaptation of imager based reading technologies rather than the use of lasers in the future. The use

of imagers will permit the reading of all symbology types, image capture, signature capture, and it will also create more reliable reading systems that have no moving parts to wear out. The selection of technology will be limited by the real estate available for the product marking / identification, and whether or not high speed reading and verification systems exist that can verify the quality of those printed codes at production speeds. At very high production speeds, those systems exist today for datamatrix. For RSS codes, those high speed readers should be available within several months. That makes the next critical question, the issue of whether or not the technology exists for creating adequate quality codes with the on-line printing methods available. At this time, very high speed print capability exists for both static and sequential datamatrix codes. Currently, medium speed static RSS codes are possible with on-line printing methods. For medical devices, there are many laser technologies that can currently print the smallest datamatrix codes but none that are currently printing extremely small RSS codes.

Practical limits of the Symbologies.

The practical limits of the symbologies, are determined by the printing method to be employed, and the reading devices available, at the point of use. It has been commonly said that the limit for RSS codes is 6.7 mil on labeling. That is true for excellent quality print. However, past testing of the printing methods used in the real world in the pharmaceutical industry, showed that printing and maintaining quality below 8 mil is problematic. If on-line printing methods are employed such as high speed thermal transfer, the 300 dpi limit of these print heads may make 10 mil dot size what is the most maintainable in the real world. The newly developed 600dpi thermal transfer print engines are too slow for all but the slowest of production lines. The ability of CIJ (Continuous Ink Jet) Systems to maintain readable high density RSS codes is extremely questionable, but much more readily accomplished on datamatrix with it's more forgiving error correction. Extremely large messages could be created with either RSS or datamatrix codes, should they be required, and if the printing methods are adequate.

How are bar codes used now, and how should they be used in the future?

At this time even the existing bar codes are underutilized. They are primarily used at present to assure packaging component verification on the pharmaceutical packaging line. Adaptation of automated reading technology must be implemented at the point of use / dispensing for the advantages inherent in using automatic data capture and verification to be realized. If such adaptation is not implemented, this additional identification will be largely wasted except for the ability to perform product recalls and implement anti-counterfeiting schemes. Currently only 1% of hospitals and care providers have the ability to read any type of bar codes.

How should medical devices be bar coded?

Due to their small physical size and the way in which they are used, most medical devices will be identified by directly etching the code into the product. This may be accomplished chemically or through the use of lasers. For the smallest of these devices only datamatrix is practical, and very high density datamatrix readers may be required. For many medical devices such as orthopedic implants (knees, hips, etc.) , these codes can be added on early in the production cycle to insure that the product goes through each production step required of it. Unfortunately the very nature of these products is that to the human eye there may be no difference if a critical production step has been missed (multiple heat treating cycles for example) , and if the paperwork associated with it is

incorrect. By having a unique ID on each product that is read at each production stage that is next in the cycle, the device can be identified, and it's movement through that cycle recorded and verified.

Costs and technical issues for consideration?

For the pharmaceutical company, datamatrix could be implemented now and present production speeds could be maintained on even the highest speed lines. Datamatrix could be more easily incorporated within limited label copy areas. On-line printing of RSS may require the use of dual printers at the highest production rates to achieve the requisite quality. In reality, poorer physical quality datamatrix codes are readable by existing technology than is the case for RSS. If only linear versions of RSS were to be used, the cost to end users may be less for RSS codes. However, if all the information that is desired to be passed to the end user is implemented, there is no real difference in the reader costs for the end user. At the point of production, many pharmaceutical companies have already implemented machine vision technology to assure readability of their printed expiry and lot codes. Most of the systems in place are also capable of reading datamatrix. None read RSS at this time, and it's addition may require both hardware and software upgrades. There is no guarantee that manufacturers will be willing to upgrade their existing systems to add RSS capability. The replacement of existing systems with new technology will not only result in capital expenditure, it will also incur the costs and delays associated with the new validation that will be required. It would be less costly and less time consuming to validate existing systems whose existing datamatrix reading capability is merely enabled.

Production Issues

At this time it would be easier for the manufacturers to implement datamatrix. In the area of label design / redesign on either the Windows or MAC platforms, most of their existing design packages either already support the addition of datamatrix codes, or this capability can be added at costs of under $500. For those designing in the Windows environment, many software packages also support RSS codes. Unfortunately, for those many art departments that design in the MAC environment, at this time only one relatively costly design package ($10,000-$12,000) is available to implement RSS codes.

As regards the production line itself, matrix codes and quality can be maintained and monitored at higher speeds and lower costs with datamatrix than with RSS at this time. As more RSS capability is added by equipment manufacturers (printers & readers), this disparity will be reduced, but will never be completely eliminated. The fact is that the error correction in Datamatrix will ensure that poorer quality matrix codes will always be more readable than RSS codes, raising production costs by increasing reject rates due to code readability issues.

Expected Benefits

Besides assuring that the correct drug is dispensed, the use of automatic data capture can streamline the recording and accounting functions. It can be used to reduce counterfeiting. If patient IDs were created that identified any allergies at the time of admission, reading of those codes before dispensing could prevent potential allergic reactions. If imager based readers are employed, signature images could be captured and true accountability established while transcription errors are reduced.

Controlling Efficacy

The addition of expiry dating and it's automatic capture as a check could be used to assure that out of date product is not dispensed. It can also be used via database to assure that the lot is an acceptable one that has not been subject to recall.

Preventing Counterfeiting

Recently product counterfeiting has become more of an issue. While many techniques can be employed that will reduce the incidences of counterfeiting (IR, UV, Product Unique Chemically Activated Indicators, Holograms, etc.), most of these can eventually be counterfeited as well. Therefore, the only way to assure that a particular package or item is unique and has not been duplicated, ultimately is to read it's unique ID and query a database over the web to determine if that package has been used before. If it has, then it should be flagged, and the location at which the number has been previously used identified, and an investigation initiated. Only by the use of such technology will the counterfeiting gap ever be totally closed. Handheld devices with the imaging technologies we have suggested, as well as the Wireless links to access networks or the web can be had for approximately $2,400. These devices could not only perform these functions, they could update all relevant databases (hospital, care provider, insurance) in real time, improving performance and reducing costs. If access to live databases is not to be considered, the use of a check digit encoding scheme that is unique to each manufacturer and identified in his product ID and calculated and dependent upon the 4 character sequential serial number that is proposed for the end of the code, should be employed to assure that the product is not counterfeit. We have developed such an encoding scheme and would be happy to provide it for use.

Small Package / Label Marking Key Issues:

On-line Printing:

While 6.7 mil print widths have been specified as the lower limit for RSS-14, real world experience indicates that most vendors and end users have problems maintaining print quality consistently below 8 mil print width. On very small labels, this will present problems with the vertical registration on the RSS composite codes. Datamatrix has room to spare.

It is recommended that where space is available, at least 8 mil RSS-14 Limited is used.

Since it is much more space efficient, 10 mil Datamatrix could readily be used and is recommended.

Using wider codes (dot sizes) with both codes allows lower resolution reading devices to be used that have more focal depth of field (a wider sweet spot of successful reading range).

At this time Datamatrix printing technology can be added to existing labelers at the cost of about $11-13,000 per line installed and acceptable results achieved. Datamatrix print verification could be added for about $13,000 per line complete with ANSI grading of the data matrix print quality in real time on every label.

At small vial line speeds (400-450 / minute), both high speed thermal transfer printing technologies, and continuous ink jet systems exist that could print the Datamatrix codes required at readable quality levels. This can be achieved with RSS-14 at lower speeds with thermal transfer print technology. The width of the RSS-14 limited code would preclude the use of Continuous Ink Jet technology at these line speeds and the stitching together of multiple heads at these speeds would not result in quality codes in the required orientation. Printing date and lot codes adjacent to the Datamatrix would optimize performance.

Datamatrix and RSS-14 Reading Devices (Handhelds):
Readers from at least 5 different manufacturers exist that can decode both RSS-14 and Datamatrix symbologies. The cost of these handheld devices begins at about $450.

Prices for a complete handheld batch data collection unit including the requisite accessories would be about $1,200 with charger and communications cradle. Costs climb from there up to the $2,500 range for the units complete with wireless communications, 2D imager, touch-screens, 32MB of Memory, and capability to connect to the internet.

With the dramatic drop in prices for imagers due to the adoption of CMOS imager technology and peripheral circuitry, it is anticipated that the cost of imagers will drop below the cost of lasers within 12 months and this downward trend on prices will continue due to the manufacturing efficiencies and the removal of all moving parts. Additionally, the use of imagers will allow for image and handwriting capture, increasing overall system security.

Datamatrix and RSS-14 High Speed On-Line Reading Devices:
The ability to perform high speed on-line machine vision reading of RSS-14 codes on line at the 400-450 vial per minute rates discussed at this time does not yet exist. Prototypes have been demonstrated that are capable of reading the code and several new products with this code reading capability should be released within the next 90 days.

High speed on-line data matrix readers from six different manufacturers are available with basic prices for the reader hardware starting at about $3,200 before any peripheral control electronics and controls are added.

We have added high speed validated installed data matrix systems to pharmaceutical packaging lines from prices starting at $8,000 cost installed / turn-key on end user lines. We anticipate similar prices for RSS-14 technology about two years from now. The initial technology required for high speed RSS-14 can be expected to cost about $16,000 and up. End users can anticipate the cost for adding such reading capability for high speed on-line use to range from $8,000 to $25,000 for high speed web re-winder applications where speeds of over 2,000 labels per minute have been reached, complete with ANSI grading of Datamatrix codes.

Off-Line Print Quality Verification:

The cost of the only Print Quality Verifier in existence for RSS-14 is $6,995. A similar cost is required for Datamatrix Print Quality Verifiers, although some can be had for as little as $4,995. At this time no one unit can currently perform print quality verification on both RSS-14 and Datamatrix although such a unit is planned for release by the end of this year.

Future Considerations:

To totally close both the existing product monitoring and recording gap, as well as the growing problem of counterfeit product, it is recommended that the use of serialized Datamatrix or RSS codes be considered. In addition to assorted chemical authentication materials, UV marks, IR marks, and other schemes (Holograms, etc.), it is apparent that only by going to a product look-up of a unique serial number can the user be assured that it is unique and has not been used before. By appending a 4 digit alphanumeric code at the end of these symbols, 1,679,616 different unique packages could be associated with a particular lot and authentication would be possible. If a number has been used elsewhere, one is not real product.

If a serialized code is to be added, at this point it could only be accomplished at high line speeds with Datamatrix. Datamatrix has been integrated into both thermal transfer and inkjet printer controller engine technologies so that it could be re-imaged and serialized on the fly, internal to the printer engine controllers, at these speeds. Most RSS codes are currently image maps that are being downloaded from the host controller and could not be re-imaged remotely at these line rates.