Data Matrix barcodes: you can't control what you can't measure

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Wyatt Earp, the legendary sheriff of Tombstone used to solve troubles in a simple way: aiming, pulling the trigger and bang! ... problem eliminated! Some manufacturers check the readability of their barcodes in the same way: pointing, pulling the trigger and beep! However, do they really solve the issue? Unfortunately, no.

Before looking at the details, let us ask why barcode quality is a hot topic for the pharma industry. The primary reason is because of the mass serialisation of folding boxes, which has been mandated by several health authorities including France and Turkey, based on Data Matrix barcode technology. Therefore, maintaining an acceptable level of barcode quality in pharmaceutical production processes will be an increasingly important task, and a legal requirement.

The error-free readability of the code should be guaranteed throughout the global supply chain. The barcode issuer is responsible for the barcode's readability by all readers, including older and even worn out readers. Just using a normal handheld reader to check the readability of the code is not sufficient because its reading quality is not defined. Instead, specialised testing equipment and measuring procedures are required, and a full range of ISO/IEC standards have been created to define barcode quality levels (grades) and measuring systems (verifiers), as well as the related testing methods.

In this article, I will show why assessing barcode quality is important and will report on some of my own experiences from the practice.

Legal requirement/needs for quality assurance

The fight against counterfeiting and the need to assure patient health are the main drivers for deploying mass serialisation on pharmaceutical products — applying a unique code to each package dramatically increases the transparency of the supply chain and makes criminal activities easier to detect. Because of the advantages, mass serialisation is being promoted by many health authorities, including those in Brazil, China, India and Spain; however the main drivers of implementation at the moment are the following:

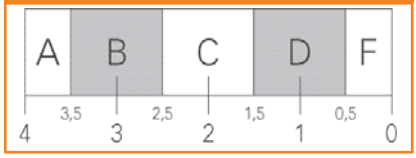
- The EU Commission has specified in the "Directive of the European Parliament and of the Council" amending Directive 2001/83/EC dated 10 December 2008 actions to be taken by member states to protect patient safety.[1] A special emphasis is on mass serialisation.
- Based on Section 505D of the US Federal Drug and Cosmetics Act, the FDA has the obligation to develop a standardised numerical identifier for prescription drug packages. In January 2009 the agency published a draft guidance[2] specifying the need for mass serialisation.
- The Article R5124-58 of the French Public Health code was amended and published in the Official Journal on 24 August 2008. It specifies that "for each incoming and outgoing transaction, the number and expiry date of all batches must be recorded together with the quantities supplied or received per batch. This shall become compulsory on 31 December 2010".[3] The outer packaging of medicinal products shall bear the CIP13 code, batch number and expiry date, marked in plain text, and ECC 200 Data Matrix marking will be used. As it is necessary to encode variable data into the Data Matrix code, in-line coding directly on the packaging line is the most appropriate solution. The code quality has to be assessed based on the ISO/IEC 15415 standard and the required minimal Data Matrix barcode quality grade has to be C(1.5) — for details regarding quality grades see the section below.
- The Turkish Ministry of Health, G.D. of Pharmaceuticals and Pharmacies has published in its guidance on the use of barcoding and identification,[4] the principles related to the identification and barcoding of medical products for human use. Article 10 mandates that the barcode quality level has to be measured based on ISO standard 15416 for linear and 15415 for Data Matrix barcodes. In article 12, it is specified that the minimal Data Matrix barcode quality grade of the barcodes shall be at least D(0.5).

ISO standards framework for assessing the barcode quality

Verifiers are required to measure the readability of barcodes. Such an instrument is normally based on a digital camera, with specific illumination and software to process the image data — the relevant design criteria and measuring tolerances of the verifier are specified in the ISO/IEC standard 15426 (parts 1 and 2).[5,6] As most barcode readers use red illumination, the verifiers also deploy red light of typically 620 nm to 640 nm wavelength. This is an important restriction because it is impossible to print barcodes in red, yellow, orange or brown as these colors are poorly visible in red light. Black, blue and green tones are recommended for printing barcodes.

ISO/IEC standards define the measuring procedures for validating barcode quality: ISO/IEC 15416[7] sets rules for linear barcodes and ISO/IEC 15415[8] for Data Matrix codes. To ensure that all instruments give the same absolute values, a global calibration standard is important. For linear barcodes, such a standard has been available for many years, but until recently a standard was missing for Data Matrix codes. Fortunately GS1, the issuing agency of the EAN 13 linear barcode, which is in daily usage on almost all products, has now developed a "Calibrated Conformance Standard Test Chart" for Data Matrix barcodes.[9] This calibration chart features seven codes with specific defects to

Figure 1: Barcode grading scale.



check the correct reading of all measuring parameters, thus assuring absolute correct levels for all numerical code quality data generated by the verifier.

Assessing Data Matrix code quality

Barcode quality is measured in grades that can be reported as numbers from 0 to 4, or as letters from A to F (**Figure 1**). Grade A(4) is the best value and grade F(0) is the worst, indicating that the code is not readable ("F" stands for Failure).

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Very often, a barcode may, at first glance, seem so perfect that even experts would consider it a high-grade code. A good example is shown in **Figure 2**; however, the code is not readable and is graded F by the verifier. Why? A macroscopic investigation shows the problem. The code is geometrically distorted, is not symmetrical and therefore does not fit into the reference grid. The lesson learned is straightforward: the human eye cannot replace a specialised measuring instrument.

Figure 2: Unreadable asymmetric code does fit in the reference grid.

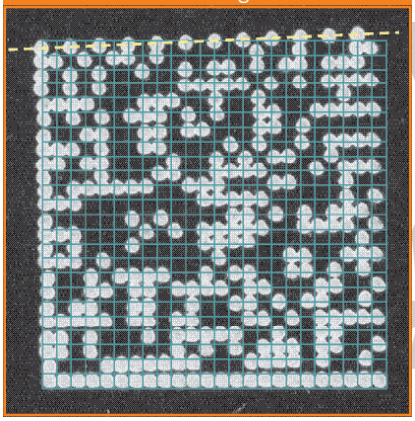
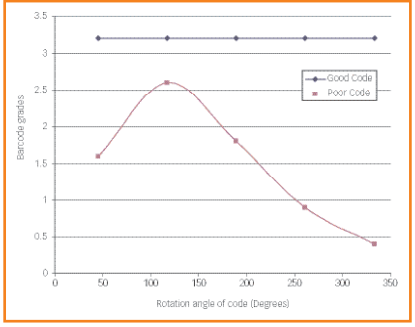


Figure 3: Influence of sample rotation on Data Matrix barcode grades.



The ISO/IEC standard 15415 mandates that the sample shall be measured five times and rotated under the camera by 72° between each measurement,[8] but there have been numerous discussions about how practically relevant this requirement is, especially as before 2009 there were no instruments on the market that allowed for a comfortable standard ISO measuring cycle. At the end of 2009, however, Compar (Switzerland) teamed up with Cognex (MA, USA) to launch a new product designed to specifically fulfill the ISO/IEC 15415 Data Matrix verification requirement.

The system enables a clear correlation between barcode grades and sample rotation to be observed by testing low quality Data Matrix barcodes. Measures of codes with geometrical distortions, such as the one in **Figure 2**, are especially sensitively to rotation — the value of the grades can vary as much as between A and F for the same code depending on the rotation angle! Data Matrix barcodes properly printed with a measured grade B or better, on the other hand, are practically insensitive to rotation. **Figure 3** shows the measuring results of good and poor codes.

In-line barcode grades monitoring

Most Data Matrix barcodes with variable data content are printed in-line on automated packaging lines. Because continuous monitoring of the barcode quality is highly beneficial, a camera system can be connected to a powerful computer to run the quality assessment calculation at high cadence. Until recently, the available computing power allowed only the use of a low end grading procedure based on the ISO/IEC 16022 specification for automatic identification and data capture techniques.[10] Unfortunately, the results of the in-line corresponding validation cannot be compared with the officially accepted data as described above because different parameters are used for specifying the grades.

Thanks to increasingly powerful computers, however, the ISO/IEC 15415 measuring procedure can now also be used for in-line quality monitoring. Because the in-line quality check is based on the same computing algorithm as the standalone verifier, direct comparisons can be made; however, we have to keep in mind that the in-line system will hardly provide the same accuracy because of limitations, such as very short measuring times, illumination restrictions, vibrations and dust. Additionally, the in-line system can only take one picture, while off-line verifier computes a grading based on five pictures taken at five different angles. Nevertheless, experience shows a good correlation of the data generated by the in-line camera and off-line verifier as long as the barcodes are of impeccable quality. For low grade codes, however, the comparability is not as good because rotation is necessary to assure accurate quality measurements.

As already mentioned, using the ISO/IEC 15415 standard requires calibrating the measuring instrument and, consequently, this obligation also applies for in-line measuring equipment. A reference chart carrying a pattern or code with a well-defined contrast is required for the calibration process.

The most effective method of supervising the Data Matrix barcode quality level of packaging lines is to implement an in-line monitoring camera system based on the ISO/IEC 15415 norm.

Checking the syntax and structure of the barcode

Data Matrix barcodes used for serialising products are, in most cases, called 'concatenated codes' because they carry structured information consisting of one or more data strings, with every one prefixed by an Application Identifier (AI). This AI is a numerical header positioned in front of each data string in the code. The AIs are globally standardised to guarantee proper decoding of the data content. Additionally, some technical characters must be present in the code to allow the reader to identify the type of code and the encoding scheme — these characters can be considered as an operating system for the code, called syntax. If the syntax and structure of a code are not both perfect, the data content of the code cannot be interpreted. Therefore, it is highly recommended that the syntax and

structure of the code are also checked during the verification process.

Recommendation

You can't control what you can't measure, and this wisdom also applies to barcode technology.

Assessing the quality of barcodes is not only a legal requirement, but is mandatory from engineering and quality assurance perspectives to assure proper system function. In fact, more and more end dealers and distributors, including Walmart, are fining suppliers when they deliver products carrying low grade barcodes![11]

The most effective method of supervising the Data Matrix barcode quality level of packaging lines is to implement an in-line monitoring camera system based on the ISO/IEC 15415 norm. Because of accuracy limitations, in-line systems cannot replace standalone verifiers, but when used together the systems complement one another; the in-line system allows screening mass production while the standalone verifier can be used as an in-process control instrument to validate rejected samples, as well as to service and maintain the packaging line. **PTE**

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