Laser coding – still the technology of choice for the Pharma industry

Introduction

The year 2011 represented a milestone in terms of the introduction of new regulations in the campaign to combat counterfeiting in the pharmaceutical industry. However, even before this date, global manufacturers had already started to introduce new coding measures to increase security in the supply chain using a range of different solutions. One such solution that is proving popular is the use of 2D data matrix coding (DM).

To date, laser coding technology has been the preferred choice for the pharmaceutical industry, but with the increasingly complex coding requirements, some may argue that lasers have reached their limit. Or have they?

Anti-counterfeiting in the global pharmaceutical industry – who will bring order to the chaos?

Fuelled by the rise of freely available products via the internet, the incidence of fake, mislabelled or unauthorised products reaching the open market is on the increase, resulting in huge losses in sales revenue for the global pharmaceutical industry. Today, this represents a significant grey industry anticipated to be worth billions, touching Europe, America, Japan and the emerging markets. More worrying, these counterfeit products are responsible for an estimated 2,000 deaths every day throughout the world*.

*source: Healthcare Packaging Issue Jan 2012

Typical scribing laser code in the pharma industry – four lines of text plus 2D data matrix code (DM)
While still waiting for the final details of the FMD to be announced, it is widely anticipated that the regulations will include some form of 2D data matrix code (DM). This is a two-dimensional symbol capable of storing a large quantity of information. At approximately 30 times smaller than a Code 39 bar code, the DM code is one of the smallest and most dependable bar code symbols available today. Furthermore, its storage capacity is far greater than the more traditional linear barcode (ID), which is much more limited.

Therefore, with the exception of China, the majority of countries are proposing the use of the ECC200 2D data matrix code as the machine readable code data carrier of choice, albeit with some differences. France and Turkey are good examples, in which both countries are using a 2D DM code, but the French CIP13 code doesn’t incorporate item-level serialisation, while the Turkish ITS codes includes non-random numbers.

Even though most countries use a DM for their anti-counterfeit measures the code format varies from country to country.

To fight this global threat to the industry and ultimately to patient safety, many countries are starting to implement anti-counterfeit measures. In February 2011, for example, the EU adopted the Falsified Medicines Directive (FMD) 2011/62/EU which incorporates a series of initiatives to help safeguard the supply chain.

These will include obligatory sophisticated identification and authenticity features on the outer packaging of medicines, including item-level serialisation in the form of a unique, non-predictive number using machine readable codes. By 2016, these new stringent regulations will become mandatory and all member states will need to have found a solution to enable manufacturers to comply.
2D DM coding at high line speeds – lasers still first choice?

With the introduction of DM codes, the complexity of product identification has certainly increased over the past few years and is likely to continue to become more demanding in the future. When it comes to choosing the right coding technology, scribing lasers have always been one of the preferred choices in the pharmaceutical industry due to a number of advantages over alternative coding methods:

• cleanliness of the coding process
• high reliability and greater productivity (through lower maintenance and downtime)
• instantly permanent coding requiring no drying time
• greater water and UV resistance

With the increasing complexity of product coding, and the demands for ‘on the fly’ 2D DM coding onto pharmaceutical cartons at higher speed production lines (currently reaching production rates of 500 packs per minute), there have been concerns that laser coding may be reaching its limit.

But are these concerns over the performance limitations of lasers actually only due to physical constraints? Or can existing laser technology be improved in order to fulfil these complex coding requirements?

At the Laser Centre of Excellence of Domino Printing Sciences based in Hamburg, Germany, the expert laser teams have been asking those exact questions and undertaking extensive research to see how new developments and advances in laser technology can address these more complex coding requirements.

Working alongside several pharmaceutical OEMs and suppliers, and undertaking a number of tests within a range of pharmaceutical applications, the Domino team has been able to identify and understand the issues preventing successful DM coding with lasers in high speed production environments. Furthermore, with this new understanding of the critical factors, it has been able to determine the optimum composition for laser-friendly material for 2D DM coding.

Room for improvement?

A 2D DM is much more sensitive to misalignments or product handling issues than human readable text. Human readable text experiencing slippage or unplanned movement during the printing process will still be readable by the naked eye. Data matrix codes however need to capture a high density of data in a very small grid which, in turn, needs to be decoded by a vision system. Even small deviations in a DM might result in the verification grading, against ISO/IEC 15415 Evaluation Parameters determining the quality of the code, falling below compliance standards (grade A & B are recommended). Deviations such as Grid Non-Uniformity, which is a symbol’s cell deviation from the ideal grid, or more obvious factors such as limited code contrast, should therefore be avoided in order to ensure good grading and readability.

Grid Non-Uniformity refers to a symbol’s cell deviation from the ideal grid of a theoretical “perfect symbol”.

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Domino is able to advise machine manufacturers to minimise vibrations that could potentially have a negative effect on the laser code quality.

**Material Properties**

Composition of the substrate is a further area which can affect the quality of code. Printed cardboard is the most frequently used material in laser coding applications especially in the pharmaceutical industry. Although cartons look similar, the differences in the actual substrate are immense and this in turn can affect the output of the code.

Traditionally these materials were optimised for offset and ink jet printing processes, and to date, little effort has been made to develop special “laser-friendly” cardboard materials.

Laser coding works by means of ablation of ink layers onto cardboard. The key issue appears to be that the mineral layer must absorb strongly at the laser wavelength to locally heat up and subsequently evaporate the overlying ink layer.

With the use of our in house Fourier transform Infra Red spectrometer, the Domino team analysed a range of common cartons used in pharmaceutical packaging. The results identified the peak absorption of the two commonly used mineral pigments determine the energy needed for a good code quality. A material with a low threshold energy density (optimum carton composition for laser) has three major advantages:

- Less power is required
- Whiter codes with greater contrast and readability (compared to browner shades which is common on higher threshold substrates)
- Less dust (resulting in a reduction in cleaning downtime, and lower extraction filter costs)
Innovations in laser coding for 2D data matrix applications

To assess the findings in a real production setting, Domino installed lasers into an Uhlmann carton machine with the challenge of a relatively high speed and a low product pitch. With a good quality carton material (low threshold) and correct adjustments of the laser head, the cartons were successfully coded with a typical pharmaceutical French CIP code at 500 packs per minute (with a line speed approx. 52 metres per minute). Furthermore, the DM code achieved a “grade B” when verified against ISO15415.

To further improve the grading, Domino developed a special method to create the pattern of the DM code. With the new writing method, the so called “Lines Mode”, the code is no longer composed of triangular dots but of lines (where two or three lines form one module of the DM code). The traditional DM Code was developed under the assumption that the modules (comprising single “dots”) are square. This is obviously not the case with DMs coded in circle mode. Depending on the size of the dots, there is more or less black “missing”, i.e. modules that should be totally black (or white) are only 70-80% black (or white).

As a result of this composition, it is very difficult to get a “grade A” in the symbol contrast category of the verifier. This is especially true for high threshold materials where the dots can be quite small. However, by using the ‘Lines Mode’ method, the modules can be “filled” completely.

When switching to the new ‘Lines Mode’, the French CIP code could be coded at 500 cartons/min and achieve a Grade A when scanned by the verifier.

In addition to improved grading the Lines Mode has additional advantages:

- Less particle creation and therefore lower extraction filter costs
- With laser-friendly materials faster than the circle mode
- More robust on most conveyor systems

When taking into consideration all the critical factors affecting quality coding output, and taking advantage of all the new coding methods and improved packaging materials, achieving standard rates of 50-60m/min for typical pharmaceutical codes is therefore no longer an issue.

However, where production speeds reach much higher levels that standard rates in certain applications, will lasers still be able to cope?

Take for example an application outside the cartoner at a separate conveyer, where the product pitch can be quite large. To achieve the desired product rate of 500p/min, these machines run at speeds of up to 90 m/min. For a typical French CIP code application with a 24x24 DM code and 4 lines of text, this is extremely fast.

When using the new method for these types of applications, an additional innovation comes into play: Domino’s i-Tech RapidScan.
This new and unique patented technology from Domino uses the optimum configuration of the mark field. The usable mark field is increased in length, giving the laser more time to produce the code which has a positive knock-on effect on the possible speed (at least 20% faster).

When combining ‘Lines Mode’ with Domino’s RapidScan, a large product pitch and a low threshold material, a typical French CIP code could be achieved at 100m/min.

Summary

At the beginning of this white paper, the question was raised as to whether laser coding technology had reached its limit for more complex pharmaceutical coding.

The answer to this question is quite simply NO, and the evidence within this document demonstrates that there is still huge potential for laser coding to remain the ideal choice in the pharmaceutical sector.

Having analysed all crucial aspects with regards to 2D coding with lasers for a number of years, the Domino team of experts have gained a wealth of knowledge and expertise to help uncover the potential of laser coding. They have identified that the most critical factors affecting the quality of output, were the composition of item substrate and the alignment of the laser at point of installation.

However, it is clear that when certain procedures and settings are followed before and during installation, lasers can still deliver high quality 2D codes onto carton board at speeds of up to 100 metre per minute.

Domino offers a series of technical workshops for its customers and partners, designed to share its acquired knowledge and assist in the development of successful solutions for data matrix applications with lasers. In addition, Domino’s application team can advise machine manufacturers how best to present and calibrate its solutions in order to maximise the quality of the laser code output.

Please contact Domino if you wish to talk to us about a lasers solution for your 2D application. We are happy to assist.