Pharmaceutical Packaging Serialization: Evaluating Coder Technologies to Print High-Quality Alphanumeric and DataMatrix Codes





PHARMACEUTICAL PACKAGING SERIALIZATION:

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Pharmaceutical and Life Sciences/Healthcare packaging operations are held to demanding internal standards and healthcare industry requirements. These standards promise to grow in complexity as (1) packaging operations serve an increasingly global customer base, and (2) serialization requirements continue to be deployed across a number of countries. Life Sciences packaging needs have

driven innovation in the coding and marking industry in the recent past and will continue to do so for the foreseeable future. Over the last decade, real needs related to high resolution printing, serialization and printer cleanliness have fueled continued development of existing printing equipment and the introduction of new print technologies.

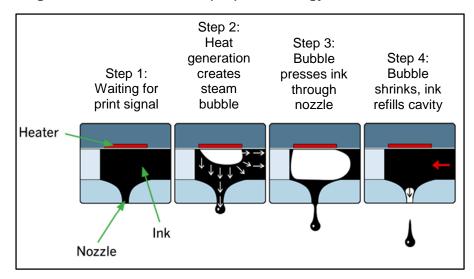
Packaging engineers and managers now have several printing technologies to choose from to meet their needs. Improperly applied, the coder selection can be a source of frustration that can drag down the speed and productivity of packaging operations. Properly specified and selected, the coder can and should be an important, yet unobtrusive, element within packaging line operations. With increasing frequency, packaging leaders are being asked to specify between the two most common print technologies for serialized marking: laser and thermal ink jet (TIJ).

This paper will focus primarily on DataMatrix printing. As many of the readers of this paper are aware, the DataMatrix code has become the standard code carrier for a number of regional and country-specific serialization initiatives. That said, the comments and recommendations contained within are applicable for a range of applications requiring high quality coding and marking.

Technology Overview

Both laser and TIJ printing provide high-resolution codes suitable for the detail required for DataMatrix symbols and multi-line printing. TIJ printers fire tiny ink drops onto packaging as it passes by the cartridge, or printhead. These ink drops are propelled out of a row (or rows) of fine-gauge nozzles by the rapid cycling of a small resistor underneath each nozzle. These resistors boil a small amount of ink which creates a small steam bubble that propels the ink drop (see Figure 1). In contrast, lasers coders use a focused beam of light to inscribe or physically alter the top layer of a substrate. The beam of light is steered by two mirror galvanometers which direct the laser beam in two planes (see Figure 2).

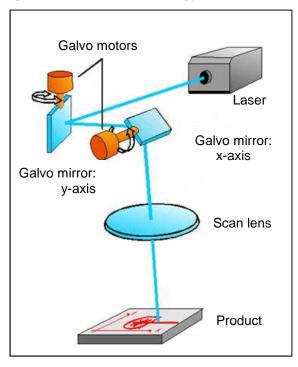
Figure 1 – Thermal Ink Jet (TIJ) Technology



To identify the right technology for a given application, the following criteria need to be considered:

- Substrate
- Speed
- Substrate handling and transport
- Installation considerations
- Cost (capital and operating)

Figure 2 – Laser Technology



Substrate

The material being marked – the substrate – should be the first consideration criteria. Of the two technologies, TIJ is more limited in substrate application and this factor can often simplify the choice for the packaging engineer. That said, both technologies require some consideration for substrate selection and preparation.

The best TIJ inks are water-based; therefore TIJ is ideally suited for applications where the ink is being applied to porous or semi-porous substrates. Pharmaceutical cartons and paper label stocks typically have an aqueous overcoat to protect the packaging material and this glossy overcoat prevents the proper absorption and drying of the ink. To overcome this, the area where the code will be applied (the print window) requires the overcoat to be eliminated. This is easily accomplished by asking the packaging supplier to modify the last step in the printing process to avoid placing aqueous overcoat over the print window. This step is commonly referred to as adding a "knock-out" to the packaging.

With this modification, it is then possible to achieve fast ink drying times of 1 second or less – which is critical for most packaging operations to avoid smearing of the printed code downstream of the coder.



Lasers offer greater substrate range with the potential to mark on paper, plastics, metal and glass. The most common pharmaceutical applications will require marking on paper (cartons and labels) as well as some plastics and metal foils (label materials and sealing / barrier materials). In these

applications, the laser mark is formed most commonly via ablation (CO₂ and Fiber lasers physically burn the top layer of material). There are two considerations when it comes to verifying suitability of the substrate with laser technology: (1) absorption of laser light and (2) creating a print window with sufficient contrast for high quality bar codes. Absorption is a function of the substrate and the selected wavelength of the laser. This criterion should be verified by the coding and marking supplier. For proper code contrast, it is commonly required to modify packaging with a print window of dark ink, referred to as a "flood fill". The laser burns off the top layer of dark ink to expose the lighter underlying substrate – making a negative image. Lasers can slightly yellow the underlying substrate, and this can result in lower can result in lower bar code contrast (see Figure 3).

Figure 3

Bar Code Grade Parameter	Code Examples		
Symbol Contrast			

For optimum results, packaging can be specified to include a layer of white ink with titanium dioxide or calcium carbonate to be applied before the flood fill is applied. This boosts the reflectance of the white part of the code, and can improve bar code contrast and readability.

Packaging line speed

Packaging engineers need to ensure valuable assets like packaging machinery and skilled operators are being utilized as efficiently as possible – therefore line speed and throughput are key decision criteria. For TIJ, maximum line speed is a simple calculation governed by the selected print resolution of the code (in the direction of substrate travel) and the maximum speed at which the resistors can be

turned on and off (the firing frequency). The complexity of the code (e.g. 2 lines of text vs. 4 lines of text) does not impact maximum line speed since TIJ technology can fire all nozzles simultaneously – one of its key advantages. Therefore, a four line code with a DataMatrix bar code can be printed at the same line speed as a simpler two line lot and expiration code. This aspect of TIJ technology is a helpful reassurance for packaging engineers that anticipate adding code content in the future for internal traceability or external (e.g. regulatory) requirements.

Calculating maximum laser line speeds is a bit more complex than TIJ since multiple factors influence maximum line speeds. These factors include:

- Substrate how much energy (time) is needed to ablate the material to form the code?
- Lens size / marking field size how much time does the laser have to "engage" the product for marking?
- Code size and complexity how much code content is required and how much total time is required to form the code?
- Product pitch how closely spaced are the products and how does this impact the amount of time the laser can engage the lead product before transitioning to the product immediately following?



For the majority of the common pharmaceutical applications described earlier, a typical 30-watt CO₂ laser or 20-watt Fiber laser offer very competitive line speeds compared to TIJ technology. As the substrate becomes more challenging (e.g. plastics, foils, metals), this may require longer mark times and slower running lines. But these applications fall outside of the application

window for TIJ – making laser the default technology. A coding and marking specialist should assist in the application assessment given the multiple factors detailed above.

Substrate handling and transport

Both lasers and TIJ printers require smooth, vibration-free transport of the substrate in order to provide the highest quality codes. Lasers must be properly integrated into the line with robust mounting hardware to ensure there is no vibration during operation and the plane of the marking lens is held perfectly parallel to the substrate being marked with one axis of the marking head at 90 degrees to the direction of substrate travel.

Both technologies can operate in continuous and intermittent (stop and go) packaging applications. An advantage of laser is its ability to print on either moving or stationary packaging. By comparison, a TIJ printhead requires the substrate to traverse across the front of the printhead in order to apply a code. Alternatively, the TIJ printhead can be physically traversed across a stationary substrate, but this adds some mechanical integration to the packaging line.

Some application examples include:

Continuous: carton coding

Continuous: web-based printing

Intermittent: bottle labeler

Intermittent: medical pouches and blister pack lines

The maximum allowable distance between the coder and the substrate to be printed varies between a TIJ printer and a laser. By design, TIJ printheads must be placed very close to the substrate. Typically, this distance, referred to as "throw distance", should not exceed 2 mm for high quality DataMatrix codes. Variation in excess of 2 mm can result in fuzzy characters and unreadable DataMatrix codes (see Figure 4). Lasers offer some advantages relative to TIJ – both in terms of the distance between the focal lens and the substrate and the allowable variation in product placement. A typical carton coding application may require a 100 mm focal distance with an allowable tolerance of +/- 3 mm for the position of the package relative to its nominal marking position. This incremental tolerance provides some margin of safety with respect to material handling.

Figure 4

1 mm throw distance



- Crisp modules
- Excellent edge acuity

4 mm throw distance



- "Fuzzy", ill-defined modules
- Drop placement accuracy degrades

Installation considerations - TIJ

Despite the throw distance limitation of TIJ, the technology is inherently clean and the printheads are relatively small, aiding integration into packaging lines. As described earlier, sub-second dry times are achievable with leading inks and guide rails should be appropriately positioned to avoid contact with the printed code immediately downstream of the printer.

Installation considerations - Laser

Laser marking technology requires two additional considerations for proper and safe installation: beam enclosures and fume extraction.



For operator safety, enclosures need to be installed that prevent access to the laser energy during normal operation. These enclosures should include interlocks for access doors and warning labels on all removable panels. If material handling considerations prevent the full enclosure of the laser system, beam shields should be employed directly surrounding the marking head. For CO₂ lasers, polycarbonate and acrylic are acceptable beam shield materials. For Fiber and Nd-YAG lasers, enclosures should be constructed of sheet metal. Additional details can be found in ANSI standard



Z136.1.

The ablation process for laser marking creates fumes that contain small particulates and gases that may be a health hazard. The lasering of chipboard cartons and paper labels will also result in particulates that could be inhaled by line operators. Best practice for any laser installation includes the deployment of fume extraction with a filtration system. Typically three levels of filtration are employed: a pre-filter for course particulates, a HEPA

filter for fine particulates, and a chemical filter to trap gases and eliminate odors. A coding and marking specialist can provide guidance on both of these elements in a laser installation.

Cost (capital and operating)

In today's business environment, the cost factor is obviously a key consideration, and laser and TIJ offer two different capital acquisition models. On total cost of ownership, TIJ and laser can be competitive solutions, however TIJ has a lower capital cost than laser technology. This advantage is magnified whenever multiple print locations are required on a given substrate. TIJ coders have the opportunity to add several printheads to a given controller – providing an easy way to print on two (or more) sides of a given carton or printing on multiple lanes. Lasers benefit from eliminating the need for inks, but operating budgets should take periodic filter replacement into consideration. The frequency of replacement will be governed by the amount of filter loading based upon the amount of debris / fumes for the given substrate and the throughput and utilization of the packaging line. A coding and marking specialist can provide a customized cost comparison of these two technologies, taking into consideration the unique requirements of a given application.

Conclusion

As this paper explains, there are a number of factors that should be evaluated when selecting between laser and TIJ coding technologies. Other than substrate, there is no criterion which single-handedly tips the decision in one direction or the other. A coding and marking specialist with knowledge of both technologies can evaluate the specific needs for a given application, assess anticipated needs for the future, and make application-optimal recommendations. With this advice, companies can then apply their own rankings to this set of consideration criteria to make informed decisions about the best marking technology for their packaging operations costs.

More information

For more information on thermal ink jet and laser printing for pharmaceutical applications, please contact Videojet Technologies Inc. at 800-843-3610 or visit our website at www.videojet.com.



Videojet Thermal Transfer Ink Jet (TIJ) Printers

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- Excellent for porous chipboard and semi-porous substrates
- Compact design with multiple printhead options
- Webserver and advanced communication protocols to aid integration



Videojet Laser Marking Systems

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- Suitable for chipboard, metal, glass, and plastic substrates

Videojet Technologies Inc.

1500 Mittel Boulevard ● Wood Dale IL 60191 Phone 630-860-7300 ● Fax 800-582-1343

www.videojet.com • info@videojet.com

