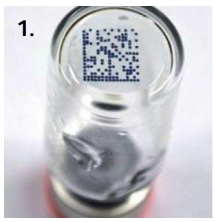
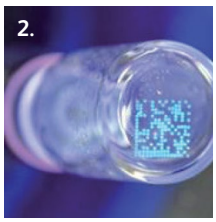
Application note

Pharmaceutical and Medical Devices

Achieving Item Level Traceability on Small Pharmaceutical Packaging (Vials)





Finding a Coding Solution to Meet Traceability Regulations

As regulations are implemented requiring item level traceability, packaging process changes will be required. In vial marking, final labeling is often completed post-autoclave, so there is a real need for an "on-vial" traceability code to ensure the integrity of the data throughout the packaging process.

A top 10 global pharmaceutical company recently challenged its suppliers to develop a solution to print high quality traceability codes on vials. The challenges included:

(a) Premium placed on code quality

(b) The available "real estate" for the given code was quite small requiring precision in code placement

(c) The vial form factor required specialized material handling which demanded tight integration with the coding and marking devices

(d) Vials would be subjected to an autoclave process downstream of the coding station, requiring a mark with suitable resilience

Big Improvements for Small Packaging:

To address its customer's requirements, Bausch+Ströbel approached Videojet to identify the right coding solution. Bausch+Ströbel is a leading international manufacturer of primary packaging systems for pharmaceutical products such as ampoules, bottles, vials, single-use-syringes and cartridges. Its highly-precise material handling solutions, including vaccum starwheels, provided the smooth, vibration-free transport necessary for printing high quality DataMatrix codes.

The challenge:

Item level traceability requirements are challenging Pharmaceutical packaging engineers to identify novel coding solutions to small form factor packaging. Coding on vials is an excellent example of this challenge due to their small size and the complex sequence of packaging operations.

Currently, traceability codes placed on the crimp seal (either laser or ink jet marked codes) are challenging to read, due to a combination of factors including line speed, contrast and the need for vial orientation to present the code to the machine vision camera.

Videojet advantage:

Videojet offers a range of products and support to deliver high quality traceability codes for small packaging. Advantaged printers coupled with a broad portfolio of inks produce high quality DataMatrix codes. Long-standing relationships with pharmaceutical OEMs allow Videojet to ensure its printers are properly integrated as part of a full system.

1. Black continuous inkjet code on glass vial bottom
2. UV ink code on glass vial bottom

BAUSCH+STRÖBEL®

Working closely with Bausch+Ströbel, Videojet proposed their continuous inkjet (CIJ) printer with 70 micron nozzle and ultraviolet ink solution.

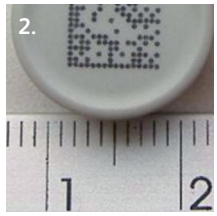
Drop placement accuracy and code quality were delivered by the inherent features within the printhead of the CIJ printer. The advanced printhead features automatic set up and calibration and auto-adjusts to changes in temperature and viscosity, ensuring highly precise drop placement throughout the production run.

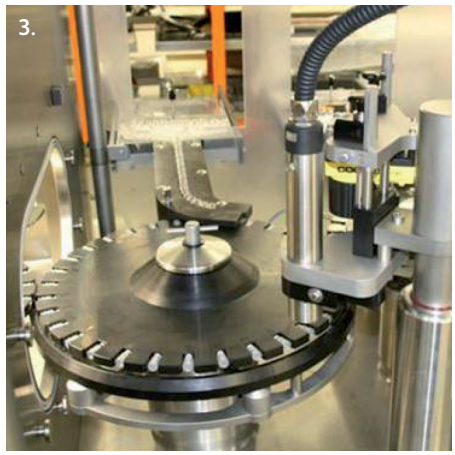
In addition to its advanced printhead, the Videojet CIJ unit offered other distinct advantages to facilitate high uptime marking on vials:

- Standard positive air and auto-cleaning printhead to deliver long runs between cleanings and fast, easy startup
- Microchip on fluids cartridge to confirm the correct fluid is being used, preventing errors
- Self-contained cartridge with needle and septum design to eliminate fluid spills

The Videojet D ultraviolet ink was selected since it addressed a number of application requirements including high fluorescence, outstanding edge acuity on plastic and glass surfaces, and excellent adhesion and resistance to autoclave processing. The Bausch + Ströbel solution includes an integrated inspection station to provide further assurance of code quality.

The combination of superior material handling, the advanced printhead design, and the Videojet high performance ink has delivered the DataMatrix code quality required for this demanding application.





The bottom line

Operational since the summer of 2010, the Videojet continuous ink jet printer installed on the Bausch+Ströbel equipment has delivered the high quality codes necessary for the customer's traceability requirements.

The features inherent in the printer design continue to deliver the reliability and uptime that is needed for this highly automated packaging operation.

1. Needle and septum ink cartridge connection helps eliminate spills
2. 2D inkjet code on vial stopper
3. CIJ printhead mounted above Bausch+Ströbel vacuum starwheel

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