Application Note

VIDEOJET PHARMA LINE

Pharma & Medical Devices

Technology Solutions for UDI Compliance

The Challenge

In 2013, the Federal Drug Administration passed legislation mandating a Unique Device Identification (UDI) code on most medical devices distributed in the United States. Compliance requirements began in September 2014. Supported by the International Medical Device Regulators Forum (IMDRF), the EU and other countries are considering similar legislation.

The Videojet Advantage

Videojet offers a range of solutions that enable compliance with UDI legislation. The Videojet Wolke line of inkjet printers has been the standard for applying high quality codes on medical device packaging for over a decade. Moreover, Videojet has the largest installed base of thermal inkjet (TIJ) printers in the pharmaceutical industry globally. Videojet TIJ printers allow medical device packaging to be coded with a range of GS1-compliant bar codes which also comply with UDI legislation.

Unique Device Identification

Prior to UDI legislation, variable coding standards for medical device packaging had been largely inconsistent across the industry. This made adverse event reporting and device tracking inaccurate, cumbersome, and time-consuming. A pressing concern for public health and safety, insufficient traceability could potentially cause dangerous consequences for consumers. In an effort to improve medical device traceability, the FDA passed legislation stipulating a common set of information be conveyed throughout the supply chain. In the United States, this standard went into effect for packaging and labeling of Class III (life-saving) medical devices on September 24, 2014, with a staged roll-out planned for other classes of medical devices through 2018. Similar legislation is being considered around the world.

Under UDI legislation, each medical device must carry a unique device identification number and production data (typically batch code, lot number, expiration date or date of manufacture). This information must be presented in two formats: human readable and machine-readable. Automatic Identification & Data Capture (AIDC) typically takes the form of a linear bar code or 2D DataMatrix. Although not specified within the legislation, the GS1 2D DataMatrix is frequently selected due to its recognition as an industry standard and the space efficiency it offers on already crowded device packages. In the example below, three GS1 Application Identifiers (AI) comprise the unique device identity: (01) Global Trade Item Number (GTIN), (10) batch code, and (17) expiry date.

(01) 13579246801237
(10) A1B2C3D4
(17) 2016 07 21

Example of a code produced by a Wolke industrial printer

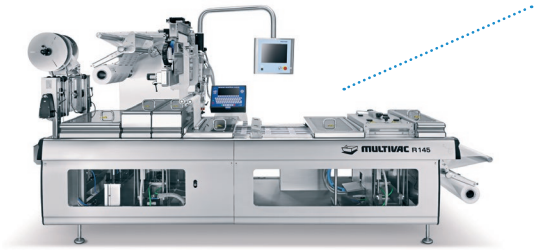
Integrating into thermoformers

Videojet TIJ printers are designed with integration in mind, as demonstrated by the numerous tested integrations with thermoformer packaging equipment. Ideally, the printer is positioned to print the code on the lidding web before it is heat sealed. The Videojet compact printer design helps enable printer placement in small footprints commonly afforded by most packaging equipment. A common approach is to have the printhead traverse across the web, coding multiple products in a single pass during the dwell (in between machine indexes when the web is stationary). This solution can drive up to four individual high-speed printheads which is ideal in that production is not compromised when spaced across individual rows of products to match the index rate.

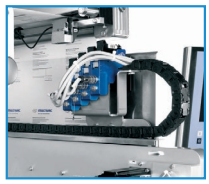
Benefits of a Wolke solution

Wolke TIJ technology performs extremely well on common lidding substrates for medical devices, such as medical grade paper or DuPont™ 1059B and 1073B Tyvek®. Additionally, the Wolke user interface provides myriad connectivity options, to support job information from an external database as well as a hand-held bar code scanner.

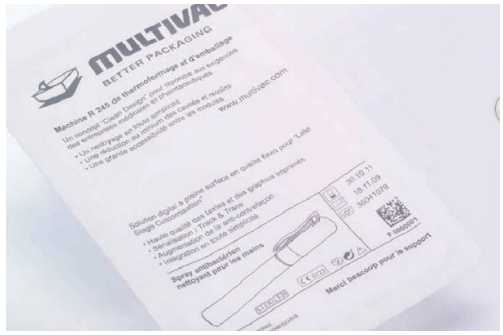
TIJ printers are capable of printing at high production speeds without compromising print resolution. With quick and easy cartridge changes in 15 seconds or less, as well as maintenance requirements consisting of a simple wipe of the cartridge print array and printhead, TIJ printers can provide extreme simplicity. Uptime is maximized through a new print array with each cartridge change to help ensure peak performance. No wear parts or maintenance consumables and no calibration procedures help reduce set up and maintenance time as well.



Example of a Wolke m600 advanced printer installed on a Multivac R145 thermoformer



Blue Wolke printheads mounted on the web of a thermoformer. The printheads move from right to left, coding multiple packages in a single pass.



Medical Device package with Tyvek® lidding

The bottom line

Preparing your line and equipment for UDI coding requires thoughtful planning. Videojet can help you identify the ideal solution for your production line. Videojet works closely with the major OEMs to help ensure our printers will integrate seamlessly with your existing lines and that your UDI coding process is perfectly suited to your business.

Ask your Videojet representative for more guidance, a production line audit or sample testing on your substrate.

Job data can be sent to the printer via a hand-held scanner

Call **0870 242 1759**
Email **uksales@videojet.com**
or visit **www.videojet.co.uk**

Videojet Technologies Ltd.
4 & 5 Ermine Centre, Lancaster Way,
Huntingdon, Cambridgeshire PE29 6XX / UK

VIDEOJET PHARMA LINE