Clearmark
/ Technology Insight

Pharmaceutical Coding and Labelling Guide

Are you FMD compliant?

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A brief summary

Are you FMD compliant?

The pharmaceutical industry is one of the most heavily regulated, with new requirements continually being introduced. The European Falsified Medicines Directive (FMD) came into force in its entirety in February 2019 and is the latest high-profile piece of pharmaceutical legislation in the EU.
However with many companies also operating in the wider global market, the specific demands of individual countries also need to be taken into consideration.

Much of the recent regulatory focus has been on the need for effective traceability systems to help ensure patient safety and tackle the growing dangers of counterfeit drugs.

With the wide variety of equipment and operating software available, companies face a myriad of choices in selecting the most appropriate solution for their particular requirements. This guide details the key factors and considerations that need to be taken into account when selecting a coding system.

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What key factors do I need to consider?

Audit trials

Each coder must be able to produce a wholly transparent ‘audit trail’ – this provides confirmation of what the coder did at any particular time, how this was implemented, and who carried out the task. To achieve this, the relevant data has to be easily transferable throughout the packing and distribution operation, and able to be accessed for incorporation into any reporting procedures.

Print & Apply labelling

For serialisation to be guaranteed in the print and apply process, the label needs to be applied to the pack immediately after it is printed – what is commonly known as ‘last label’ capability. Some labelling systems demand that a number of labels are printed into a reservoir between the print engine and the point of application. This is often necessary to allow for physical constraints and line speed fluctuations to be managed effectively; however it can add complexity and risk to the serialisation process.

As a result, the operating software will have to be adjusted to take this into account, which adds to the complexity of product and batch changes and increases the risk of errors.

Please be aware

Some print and apply labellers claim to offer a ‘last label’ facility but only by restricting the amount of space available on the label for printing, as part of it has already passed the printhead before all the data has downloaded. This is effective in terms of data and throughput, but does of course limit the print area and adds to the cost of labelling.

What key factors do I need to consider?

Usability, the benefits of a common operating system

CLARiSOFT
Label design software
CLARiNET
Networking Software
CLARiTY
Operator Touchscreen

The right software will be critical to any serialisation system in order to produce accurate, reliable and secure codes. And since many pharmaceutical companies will use different printing technologies and equipment to meet both their primary and secondary packing requirements, it is equally vital that the relevant data can be shared between the different machines via the least complicated route.

For example, if a manufacturer is printing data onto a pouch, which is subsequently placed into a carton before being packed in an outer case, three codes will need to be applied during the process. If each coder uses a different operating protocol, then linking these together may require additional software development work.of the printing technology to which it is applied.

Choosing the right supplier

Consideration should be given to selecting suppliers who can ensure that all equipment is able to operate on a common platform and which is also able to interface easily with other equipment on the line. It is equally important that the equipment chosen has a software platform which will allow easy and low risk integration with legacy equipment and software. Emulation modes and drivers are often available to ease this process.

A good operator interface should be equally effective regardless .

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What other factors do I need to consider?

What you're coding on to

The most important factor; materials and substrates. Not all coding and marking technologies are suitable for all substrates. It’s important to get this right from the start.

Speed of your production line

Some solutions move faster than others, offering more packs per minute where required, however this can be a detriment to the print quality on some technology solutions. Identify which is more of a priority for your application- speed or quality.

Print quality and readability

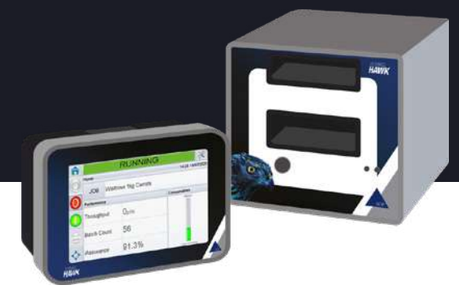
Labelling legislation and distributor requirements may determine this for you, it’s important to think about the customer and the product. For example, in the food industry, products with a short shelf life may require more data on a barcode or legally require a permanent use by date to be printed directly on to the packaging.

Readability is also crucial if you’re printing ingredients and allergens directly onto packaging, software may be required to ensure you meet the standards defined by the distributer and in accordance with the law. For example Natasha’s Law has made it a legal obligation for food businesses to include full ingredients labelling on pre-packaged foods to protect allergy sufferers.

Coder features

Variable data, embedded data, QR codes or graphics? All these will determine the size, type, speed and style of coding and marking technology required.

What is Thermal Transfer Overprinting? (TTO)



How it works

The printer uses a fixed width thermal printhead to apply ink on to flexible packaging. This is achieved by contact between the printhead and a platen or roller. Sandwiched between the printhead and the label is a very thin thermal transfer ribbon made of a polyester film which is coated on the label side with a wax, wax-resin or pure resin ink.

Typical application

Thermal Transfer Overprinting is the established technology of choice for a wide range of primary packaging coding applications such as vertical and horizontal form fill and seal machines, thermoform and tray sealing machines and a variety of flexible packaging applications. Compared to traditional contact coders such as hot-stamp or roller coders, thermal transfer overprinting traditionally offers superior print quality and lower costs.

Considerations

- The speed and precision of TTO means it is an ideal solution for printing data embedded barcodes or QR codes, which require more detail than some generic barcodes.
- The process allows for printing directly onto packaging media, and is therefore efficient in terms of process and material costs. Print resolution is typically 300 dpi.
- TTO is widely favoured but its application reach does have limitations. Due to the contact print nature of the technology, it is only suitable for flexible packaging and linear print speeds are typically restricted to about 1000mm\s if printing barcodes.

How it looks

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Thermal Transfer - ICE Zodiac Hawk

ZODIAC HAWK

THERMAL TRANSFER OVERPRINTER

An airless 53mm thermal transfer overprinter that features built-in iAssure™ print checking technology

Max throughput	Print resolution	Ribbon capacity	Print checking
500PPM	300DPI	1200M	✓

Packaging type
Primary Packaging

Printing modes
Intermittent and continuous in the same machine

Packaging material
- Vertical form, fill and seal
- Horizontal form, fill and seal
- Thermoform and tray-sealing
- Resealable pouches, stick packs and sachets

Printhead width
53mm

Print area
Intermittent: 53mm (W) x 75mm (L)
Continuous: 53mm (W) x 300mm (L)

Print speed
Intermittent: 10mm/sec – 1000mm/sec
Continuous: 1mm/sec – 1000mm/sec

Print resolution
300dpi

Features and benefits

- Top throughput up to 500 packs per minute
- iAssure™ - Integrated print checking technology identifies code legibility issues
- Conducts printing spot checks in real time, catching certain commonly occurring print defects
- Improves uptime and reduces time spent on quality checks, waste and rework
- Achieve improvements in Overall Equipment Effectiveness (OEE) by reporting on performance, reliability AND quality
- Airless, all electronic printhead design with Intelligent Motion™
- Option to mount the power supply and connection hub in the host machine control cabinet
- Easy usability with CLARiTY™ interface to ensure the right code on the right product

assure enabled

Introducing iAssure™, a revolutionary integrated print checking system helping customers to minimise production disruption and downtime.

Catches common print defects:

HOW IT WORKS

A built in sensor creates a real time image of the negative on the printed ribbon to compare with the intended image to see if they match.

iAssure™ technology determines the type and magnitude of any mismatch and determines if the code is a pass or a fail. Once a pre-set number of consecutive fails is reached, the ICE Zodiac Hawk and Falcon models can signal for a product to be rejected or stop the line entirely.

At a glance iAssure™ metrics are easily viewed on the CLARiTY™ control unit to determine the productivity of the printer.

For the first time, achieve improvements in Overall Equipment Effectiveness (OEE) by reporting on performance, reliability AND quality.

Real time view of the last print

Operator alerted to address print issue

Checking system, iAssure™, detects bad prints

What is Thermal Inkjet Printing? (TIJ)

How it works

TIJ is a non-contact process in which liquid ink is “fired” onto the packaging using thermal expansion. The majority of inks are water based and use vaporisation of the water to create the thermal expansion process. These inks must be applied to porous media to give reasonable drying times. Other ink types are available which allow printing onto non-porous media, but these often have longer drying times and may also contain MEK type chemicals.

Typical application

Thermal Inkjet technology is suitable for both primary and secondary packaging on both porous and non-porous materials.

Considerations

+ Thermal Inkjet (TIJ) is a relatively high speed process, provides good resolution and due to its non-contact nature, is suitable for printing onto rigid media.

+ Cost per print is comparable to TTO, and due to much of the print technology being contained within the disposable print cartridge, reliability levels are extremely high.

− TIJ is generally limited to use on primary packaging, or small scale secondary packages.

How it looks

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Thermal Inkjet - ICE Viper Plus

VIPER PLUS

THERMAL INKJET CODER

A zero maintenance thermal inkjet coder
with cartridge recognition and ink level tracking

free, high definition thermal inkjet coder

Packaging type
Primary or Secondary Packaging

Printing modes
Continuous

Packaging material
Porous and corrugate case packaging

Printhead width
Up to 4 printheads from 12.7mm up to 50.8mm

Print area
1 printhead: 12.7mm (W)
2 printheads: 25.4mm (W)
3 printheads: 38.1mm (W)
4 printheads: 50.8mm (W)

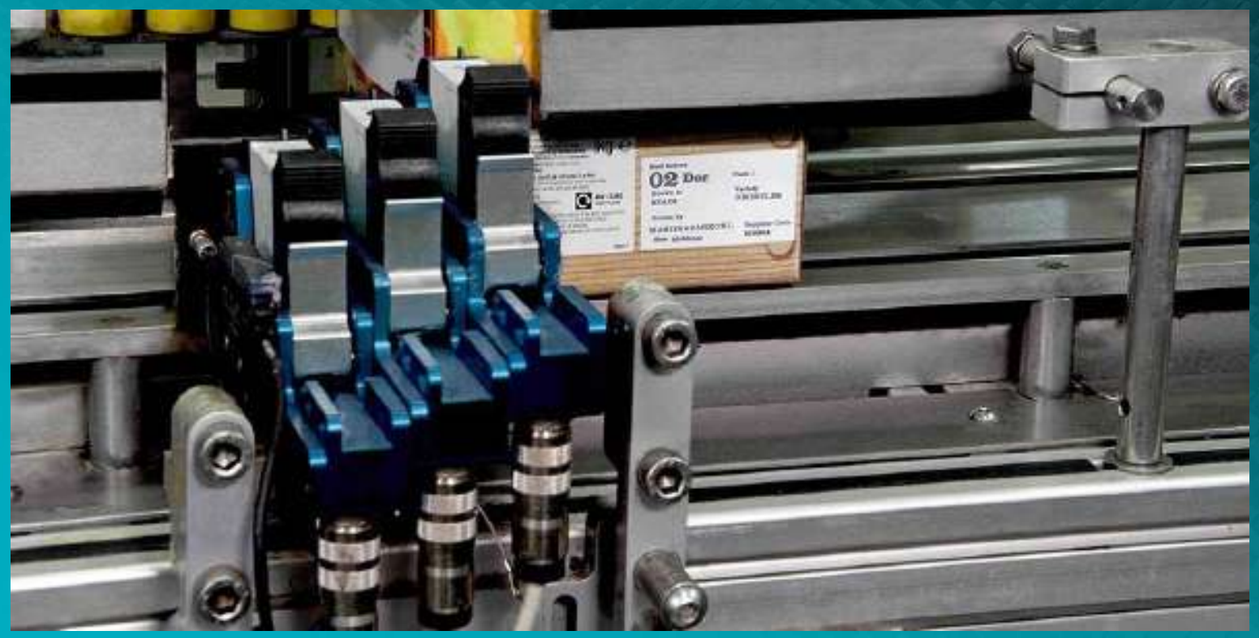
Print speed
75m/min at 600 x 240 dpi

Print resolution
600dpi

Features and benefits

- Fast consistent trouble free printing with excellent code correction.
- Print at up to 600dpi resolution, vertical and horizontal text, bar codes, 2d data matrix codes and logos
- Maintenance free printer with no replacement parts other than the inkjet cartridge – just replace the ink when required and go
- Clean, no mess and easy to change HP® ink cartridges
- Selectable ink type setting ensures that the right ink is being used*
- Automatic cartridge recognition*
- Ink level tracking that moves with the ink cartridge*

* Features available when using Genuine TIJ ink cartridges.



Flexible, high quality and scalable printing

- Fast, consistent, trouble free printing with excellent code clarity.
- Printhead configuration for up to four printheads with print heights from 12.7mm to 50.8mm at print speeds up to 75 metres per minute.
- Print up to four lines of 600dpi resolution vertical and horizontal text, bar codes, 2D data matrix codes and logos.

Reliable and maintenance free

- Maintenance free printer with no replacement parts other than the inkjet cartridge - just replace the ink when required and go.
- Clean, mess free and easy to change HP® ink cartridges.

Selectable ink type setting ensures that the right ink is being used*.

Auto cartridge recognition*.

Ink level tracking that moves with the ink cartridge*.

Intelligent and intuitive interface

- Easy to learn, quick and error free icon based controls and WYSIWYG image display with the CLARiTY coder operating system.
- On-board application qualification and technical diagnostics ensure precise set-up and maximum uptime.
- Printer cloning, parent/child mode and several methods of connectivity ensure security of data being coded.

A closer look at CLARiTY® Coder Operating System

CLARiTY ensures secure, streamlined management of data, minimising downtime and protecting brand integrity.

REDUCE…

- Rework by eliminating coding errors.
- Risk by delivering accurate legible codes.
- Recalls by consistent coding with traceability.

- Unique date calculation manager to configure offset dates, avoidance date rules and controlled concessions.
- Windows True Type fonts for flexible label design.
- Multiple language functionality.
- Intuitive high-resolution graphical user interface with icon based controls, WYSIWYG image display and colour touchscreen.
- Limited operator intervention required minimises risk of errors with sell-by dates, traceability codes, product variety and country of origin.
- USB software and image input.
- Real time view of the performance of all ICE printers in the factory.
- USB scanpoint feature allows job selection via barcode scanning with no operator intervention and no human error.
- Parent/child to control multiple printers from a single screen.
- Network capability for plant-wide solutions when used with CLARiNET® package coding network control software.
- The patented generic file structure of CLARiTY ensures future compatibility with your choice of coder. technology.
- Web browser to allow seamless OEM integration and remote diagnostics.

What is Print and Apply Labelling?

How it works

Print and apply labelling lets users create and apply labels directly onto a product and its packaging. These labels can carry data such as alphanumeric text, barcodes, serialisation, 2D codes, QR codes, addressing, personalisation, graphics and more in an accurate and cost-effective way.

Typical application

Print and Apply Labelling is typically used on secondary packaging such as boxes and shrink wrap, labelling products for shipping and storage. Some applications offer direct apply onto both front of pack and corner wrap applications, helping to automate the production line and eliminate human error.

Considerations

- Unlike LCM, this can deal with most secondary pack types (e.g. shrink wrapped cases, cardboard cases etc.) with high resolution and print quality, typically 300 dpi using thermal transfer technology.

- The equipment costs are comparable to LCM, although print quality and barcode legibility are usually higher. The technology is very clean and systems are available which can apply labels to most pack types, on almost all faces of a package.

How it looks

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Print and Apply Labelling - ICE Vulcan

VULCAN
PRINT AND APPLY LABELLER

First of its kind print and apply labeller that can print directly onto secondary packaging, without ever missing a pack.

Packaging type
Secondary packaging

Printing modes
Labels can be applied on any side of pack including wraparound

Packaging material
Traded unit boxes and shrink wrap

Printhead width
107mm

Print area
Label width / length

50 - 115mm / 50 - 300mm

Print speed
40 -500mm/s

Print resolution
300dpi / 200dpi emulation mode

Features and benefits

- No more missed packs - irrelevant of pack spacing with side application
- Print up to 150 packs per minute for typical 4”x 6” labels with top or side application
- No compressed air, eliminating constant ongoing maintenance and servicing with all wear parts removed
- Two common problematic parts removed - the nip drive roller and the pneumatic vacuum tamp applicator
- Under 60 seconds simple and quick web path for ribbon and label changes
- Easy job selection and diagnostics with a single, touchscreen interface
- Reduce incorrectly coded products with an error proof input screen
- Increased label reel size to reduce stoppages, over 9,000 labels per reel for typical 4”x 6” labels

Front of pack application

Ideally suited for cases or shrink wrapped products requiring a label to be applied to the front of a moving pack. The label is applied using a robust, pneumatically controlled arm applicator, which uses integrated pack detection and applicator sensor functionality to ensure accurate label placement every time.

Max throughput	Print resolution	Pack detection
60 PPM*	300DPI	✓

Corner wrap system

This system is ideally suited to an application that requires a single label to be applied across adjacent panels of a case or shrink wrapped product, allowing the label information to be seen from two directions. The label is applied using a direct apply printing method, and has a simple, secondary pneumatic roller wipe to ensure full adhesion of the label around the corner and side of the product.

Max throughput	Print resolution	Pack detection
48 PPM*	300DPI	✓

Tamp Applicator

The Vulcan LPA Tamp system operates using a controlled vacuum to hold the printed label and optional air blast on certain applications through a specially designed application pad. This pad has built-in pack sensing to ensure the correct pressure is applied during label adhesion.

Max throughput	Print resolution	Pack detection
60 PPM*	300DPI	✓

* Print speeds and throughput are resolution, substrate, application and set up dependent.

Get in touch

About us

Established in 2001, Clearmark Solutions Ltd has become one of the UK's leading suppliers of digital coding solutions to a wide variety of end markets including; food and beverage, pharmaceutical, printing and DIY. Today, the company operates from two purpose-built head office buildings in Nottinghamshire.

Clearmark has a 20 year strong reputation for innovation in a variety of ICE and Zebra coding and labelling technologies including; thermal transfer, thermal inkjet, large character marking, print and apply labelling.

Clearmark also custom design bespoke integration of all technologies providing the best possible Overall Equipment Effectiveness (OEE) to customers. This is all supported by comprehensive after-sales service and support. The company has a growing install base of over 2,000 customer sites.

Give us a call, we're here to help:

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