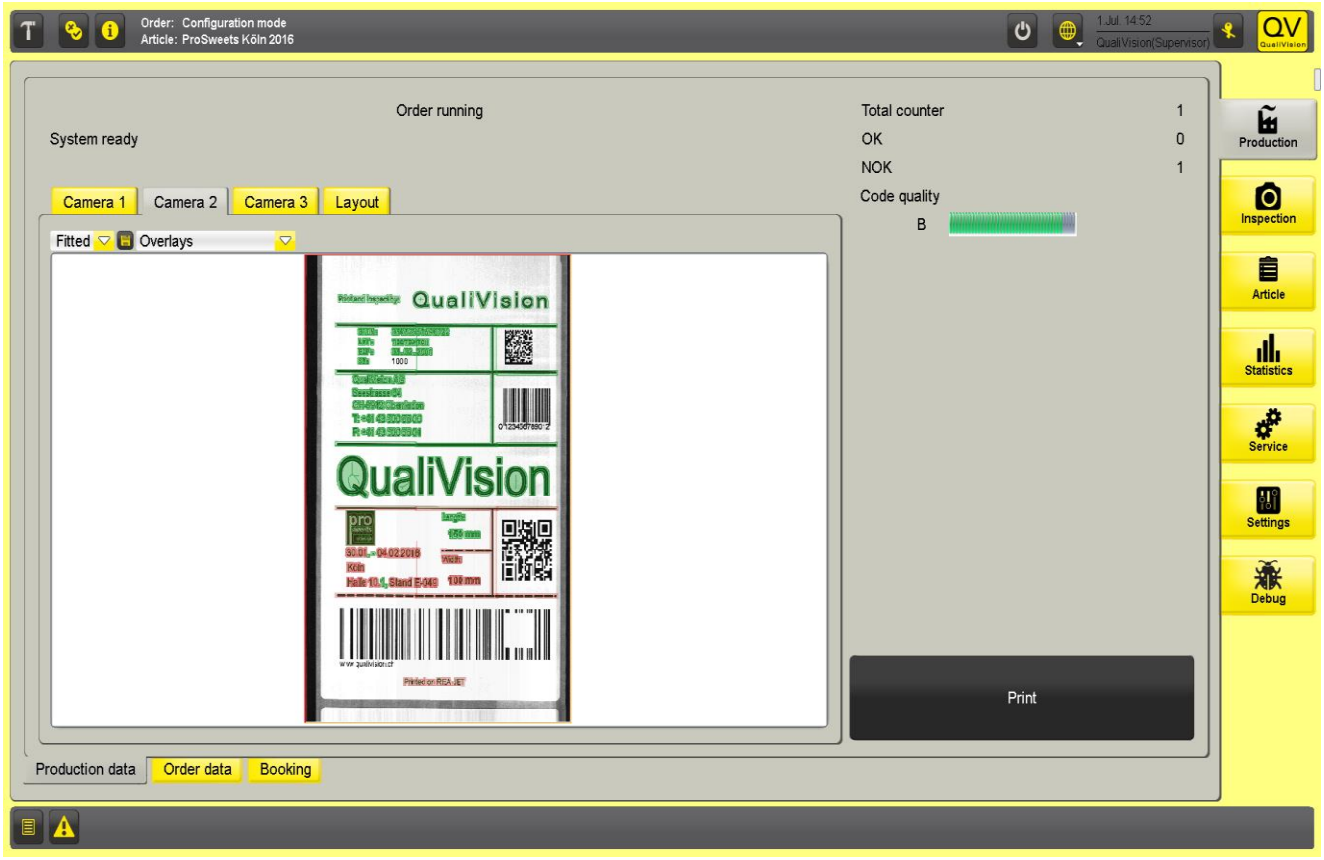
A Baumer Company

Whitepaper UDI
(Unique Device Identification)

Introduction

Compliance with the FDA's UDI conformity requirements for precise labelling of medical devices poses considerable challenges for medical device manufacturers and labelling systems. Labelling must both facilitate product traceability and enhance safety for patients. It must be possible to identify products either automatically or manually during each step of the packaging process along the entire production and distribution chain. To ensure this, product information (device identifier UDI-DI) as well as production information (production identifier UDI-PI) is printed in both code and text, in one line with coding rules. The rule is: UDI = UDI-DI + UDI-PI.



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Harmonisation efforts have resulted in the FDA's UDI systems being comparable to those used in Europe. The Official Journal of the European Union 9.4.2013 contains the following important provisions on labelling:

Definition e) "'unique device identification - UDI' means a series of numeric or alphanumeric characters that is created through an internationally accepted device identification and coding standard and allows the unambiguous identification of specific medical devices on the market. The UDI comprises the device identifier and production identifier"

Point 17: „The attribution of a unique identifier to a specific device and its use along the distribution chain (global use) will allow the unambiguous identification of the device itself."

Point 27: „The production identifier should contain dynamic information (2) identifying data related to the unit of
device production and determine the level of traceability to be achieved."

Point 28: „UDI should appear in both human readable format (human readable version composed of a series of numeric or alphanumeric characters) and in a format that can be read by an AIDC technology and conveyed via a carrier."

Point 29: "If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format should be favoured. However, certain environments or use situations, such as home care, may warrant the use of HRI over AIDC."

Point 31: „As a general rule, the information provided by the production identifier (dynamic information) should vary according to the different risk classes as follows:
— expiration date and/or manufacturing date for class I,
— lot/batch number for class IIa,
— lot/batch number for class IIb,
— lot/batch number or serial number for class III."

Punkt 34: „UDI carrier (AIDC and HRI representation of the UDI) should be on the label of the device, its package, or on the device itself (direct part mark), and on all higher levels of packaging."

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The number of different coding rules depends on the area where they are applied.

System	Description	
GS1	Products are identified by the so-called GTIN (Global Trade Item Number). Medical products need to be labelled with further attributes such as batch, expiry date or serial number. UDI rules state that both product- and additional information must be shown in text format at each stage of the packaging process. The GS1-128 and GS1 Datamatrix symbologies allow for GTIN and attributes to be coded accordingly. Several different codes are permitted.	
HIBC („Health Industrie Bar Code“)	According to FDA regulations (2013), the HIBC primary code makes up the UDI device identifier (UDI-DI). The HIBC secondary code, pursuant to FDA requirements (December 2013), is the UDI production identifier. The secondary code can be combined with the primary code directly in a 1D- or 2D-code (concatenated HIBC codes), or can be printed separately. The codes can be included in various code symbologies (Code 39, Code 128, QR-Code, Codablock F, RFID, etc.).	
ISBT 128	This standard is used to identify products of human origin (blood, cells etc.).	

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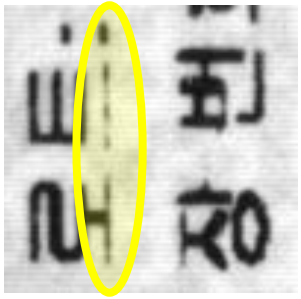
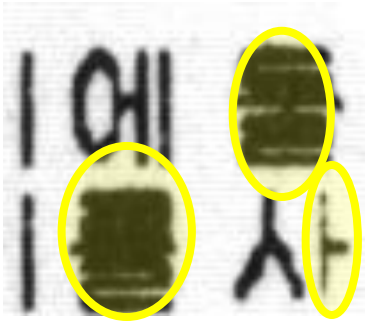
Labelling

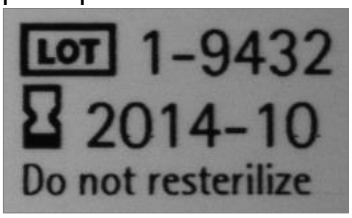
We distinguish between the following labelling methods: Print on labels or direct printing on the product itself. Various different labelling technologies are used. They all are subject to different process variations, which can impact readability and therefore entails risks, respectively can lead to errors.

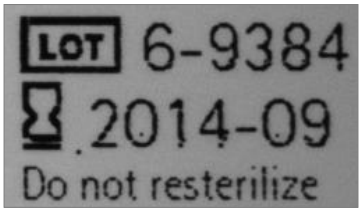
Typical problems with a thermal transfer printer:

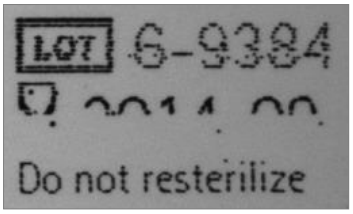




Typical problems with a DoD printer:







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Inspection

Admixture or poor print quality are a risk, and both readability of the labels and the package content must be inspected. Manufacturers implement various inspection methods:

- Code scanner: Readability of code
- Code scanner: Inspects code readability and content
- Camera system: Inspects code readability and content and checks the variable plain text data (EXP, LOT, etc.)
- Camera system: Full-surface inspection of printed data including inspection of code and plain text

Code scanner

Code scanners can read code easily and cost-efficiently. These systems have been optimised for reading and can even scan poorly printed codes. However, it should be noted that not all code scanners can handle poor print. The coding regulations applied for UDI allow for several codes. If several codes are present, it is not always possible to inspect all of them clearly.

Errors in the additional printed information such as variable data or other information may not be recognised.

Camera system

The camera can record and analyse the entire printed image. In addition to the codes, it can also inspect the variable data (EXP, LOT, etc.) rendered in plain text. Labels often contain additional important data (such as product description, size, etc.) that is specific for each country and must be printed accordingly. Globalisation frequently entails the use of character sets that make it difficult to inspect the completeness/accuracy of data.

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Code scanner versus camera system – the essentials

A full-surface inspection is more costly, but it offers benefits that only the manufacturer can evaluate.
Fewer errors resulting from misread data: Code is graded online
Safety: If several codes are present, all of them must be legible
Patient safety: Review human-readable data to check that all data is accurate
Aesthetics: Customers would like labels to show complete information
Future-proof: Recommendations do exists, but the interpretation of the relevant laws is still undecided. Presumably, the application will resemble that in the pharma industry.

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Solutions

QualiVision offers various solutions for printing and inspection, ranging from simple code scanners via vision sensors to full-surface inspection solutions (QualiReader I/PI). QualiVision systems can output directly to printers or can be used to just inspect printed data.
UDI inspection systems can be installed in printing centres, on the production line, directly at the labelling machine or on inline printers connected to machines. The optimum integration for secure and automated production can be established jointly with the customer. This also includes the software integration with MES or ERP systems and with external label layout systems (Nicelabel, PrisymID, Codesoft, etc.). Possible variations are:

- Roll-to-roll printing with inspection. Poorly printed labels are removed manually.
- Roll-to-roll printing with inspection. Poorly printed labels are automatically overprinted.
- Manual work stations with printer including inspection.
- Inline-printing and control directly on product, folding boxes or foils.

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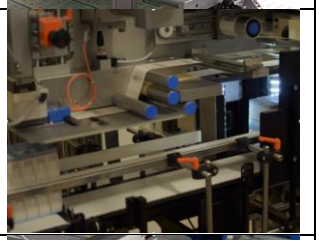
Examples of practical applications

Use	
Printing of folding boxes with thermal inkjet printer ReaJet HR During the production process, text is printed on folding boxes and is inspected with a matrix camera. Poor quality products are automatically filtered out and removed from the production process.	
Manual work station with Zebra printer 100% control Labels are printed and applied manually. Poorly printed labels must be removed and the action must be confirmed via the touch monitor.	
Variable data is printed on the blister foil Variable data is added to pre-printed labels with an HP cartridge printer and is inspected with an area scan camera. Both printer and camera are fixed to a linear axis.	
Inline printing with single-pass DoD printer Full-surface printing on blister foil and 100% control with line scan camera. The blister machine automatically omits poorly printed sections.	
Inline printing and application of labels Printing, labelling and inspection in one single step. Poor quality labels are applied and only filtered and removed later.	
Inline printing and application of labels including badtag plate Printing, labelling and inspection in one single step. Poorly printed labels are applied to a badtag/reject plate and re-printed automatically, ensuring that only clear and accurate labels are applied to the products.	

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