

EU FMD Barcode & Software Configuration Issues

Version 1

27th Feb 2019

Summary

Issues caused by incorrect scanner and software configuration

- This presentation shows four issues caused by incorrect scanner/ software set up
 - Character substitution, Case sensitivity, Data encoding order, Negative DataMatrix Barcodes
- It also shows one issue caused by incorrect software set up
 - Date interpretation
- All of these have lead to “false negative” alerts
- This needs to be addressed otherwise there will be further “**false negative**” alerts

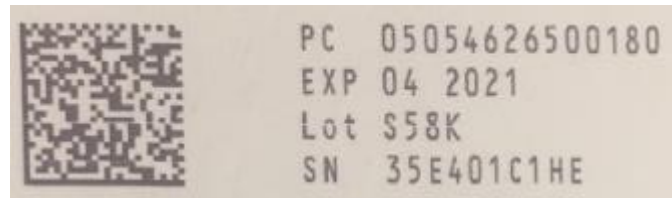
Scanners and software must be set up correctly and the configuration tested before use
This is not a manufacturers issue to resolve

International standards and protocols prevent issues

Encoding and decoding is not new – it has been done globally for over 35 years

- To work correctly, what is encoded must be perfectly decoded, otherwise the person scanning the barcode will get different information from that which is encoded

Encode



The manufacturer encodes

Decode




The dispenser decodes

The manufacturing associations in Europe agreed to follow international standards to encode

European Medicines Verification System (EMVS)

European Pack Coding Guidelines

Version 4.0
July 2017



efpia
European Federation of Pharmaceutical Industries and Associations

EAEPG
European Association of
Distributors/Pharmaceutical
Companies

medicines
for europe
better access. better health.

Examples of NTINs in use in Europe and formation rules:

Market	NTIN formation rules
Austria	908888 + PZN + check digit
France	3400 + CIP/ACL Code + check digit
Germany	4150 + 8-digit PZN + check digit
Spain	847000 + Codigo Nacional
Sweden, Finland, Denmark, Iceland, Norway	704626 + Nordic Drug Code Issued by Nordic Number office + check digit
Switzerland	7580 + Code assigned by Swissmedic (consists of 5 digits: Product License number + 3 digits Pack Size Indicator) + check digit

2.2 The Serial Number

The serial number is preceded by the AI 21 and adheres to the GS1 specification where this field is a variable length (up to 20) alphanumeric field followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field).

It is recommended that three further modifications should be considered to aide consumer readability:

- The alphanumeric range shall include the digits 0-9 and the letters of the western alphabet but exclusion of the following letters: l, j, i, o, q and u. (I J L O Q U) might help avoid confusion with similarly shaped characters/numerics.
- The serial number character string should only contain either lower case or upper case letters, not a mixture.
- Use of the extended symbols, as defined by the complete GS1 specification and documented below, should ideally be avoided.

The serial number will be unique per product code (i.e. not per batch or per product code-batch code pair).

If these recommendations are fully adopted, this gives a range of 30 different alphanumeric character options, 80 combinations if only the letter confusion aspects is adopted. 62 combinations if the case limitation is ignored and 82 combinations if the full GS1 specification is utilised. All of these options provide an essentially limitless provision of serial numbers per product SKU.

Using the GS1 specification (which is the industry norm and also represents the most mature standard available in the supply chain today), the permissible characters include the digit value 0 to 9 inclusive. Letters A to Z inclusive in both upper and lower case and the non-numeric, non-letter based extended characters: /,.,-+*)('&%"!;:<?=>_

Thus the GS1 scheme permits 82 character combinations. The full GS1 supported character set is documented in the GS1 Standard Specifications section 7.11 figure 7/11-1. http://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

European Pack Coding Guideline
Version 4

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- http://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

Character substituting

Simple intro to scanners

Why could this type of error occur

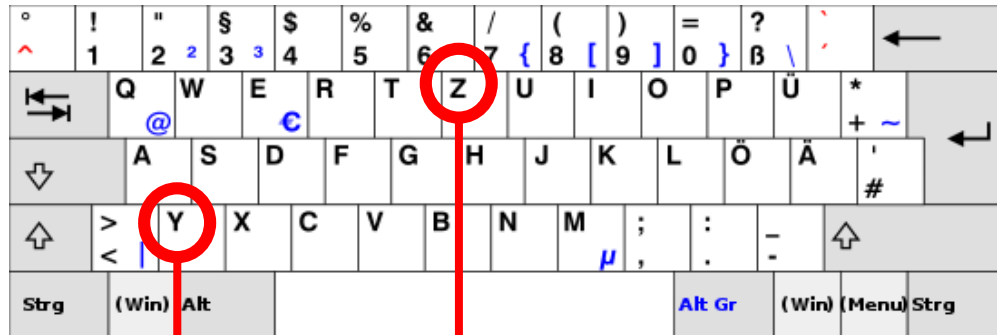


Scanners usually have one of three ways to connect to an IT system

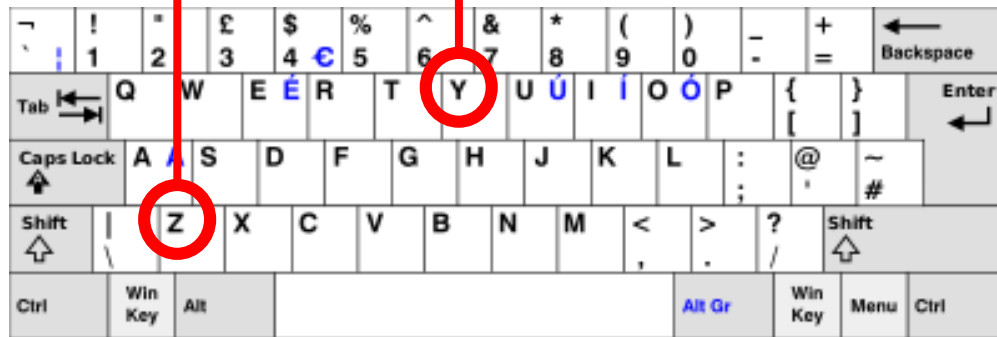
1. Keyboard Wedge Output
2. RS232 serial output
3. USB output (which is in turn uses one of the 2 above approaches)
 - USB Keyboard Wedge scanners
 - USB RS232 Serial Scanners

Keyboard wedge output

Character substitution is usual as a result of this type of scanner



Country A Keyboard



Country B Keyboard

Characters are located in different locations on the keyboard

The keyboard wedge

- This type of scanner is connected to a computer in the same way as a keyboard, in fact it is usually seen by the computer as a second keyboard
- When scanning a barcode with this type of scanner the data from the barcode enters the PC through a keyboard port as if it had been entered by a keyboard i.e. the scanner acts like a keyboard

The Issue

- Keyboard formats differ from country to country and therefore a keyboard wedge scanner set up for country A may pass different characters from a scanner set up for country B

How this is addressed - Decoding

- Providers of scanners and IT system should know that the data is encoded using international standards
- The scanning equipment and IT systems must be set up to conform to these standards and therefore ensure the data they output is the same as encoded
- Configuration and testing is vital to ensure that scanners are set up correctly especially where a keyboard wedge method is used. All GS1 characters should be tested to ensure they decode correctly.

Decode



Why not just avoid specific characters

- Barcodes are used across the world and in countries with a vast array of languages and keyboards
- The permutations are too many to consider and this would seriously limit the available characters allowed to be encoded into barcodes
- Products move across geographic locations and so it is not possible to predict the scanner type and configuration which will be used to decode a barcode
- It is far simpler and safer for both the encoding and decoding to be done in compliance with international standards
- The EU FMD is not the only use of DataMatrix barcodes and it is therefore important that FMD systems follow international standards to allow interoperability with other scanning systems

Decode



Case sensitivity

Alerts are being received with lower case characters

Based on EU directive 2011/62/EU (Falsified Medicines Directive) there was an alert generated with the following attributes:

Date and time of alert creation:	11.02.2019 13:48
Alert code:	A2
Alert ID:	CZ-0VH-9ZT-FXM-2E4
Product schema name:	GTIN
Product code:	08590335504783
Batch ID:	6g8u
Serial number:	3r8x9vm4rp
Batch expiration date:	30.06.2021

Serial number:

3r8x9vm4rp



Case sensitivity

How data is encoded



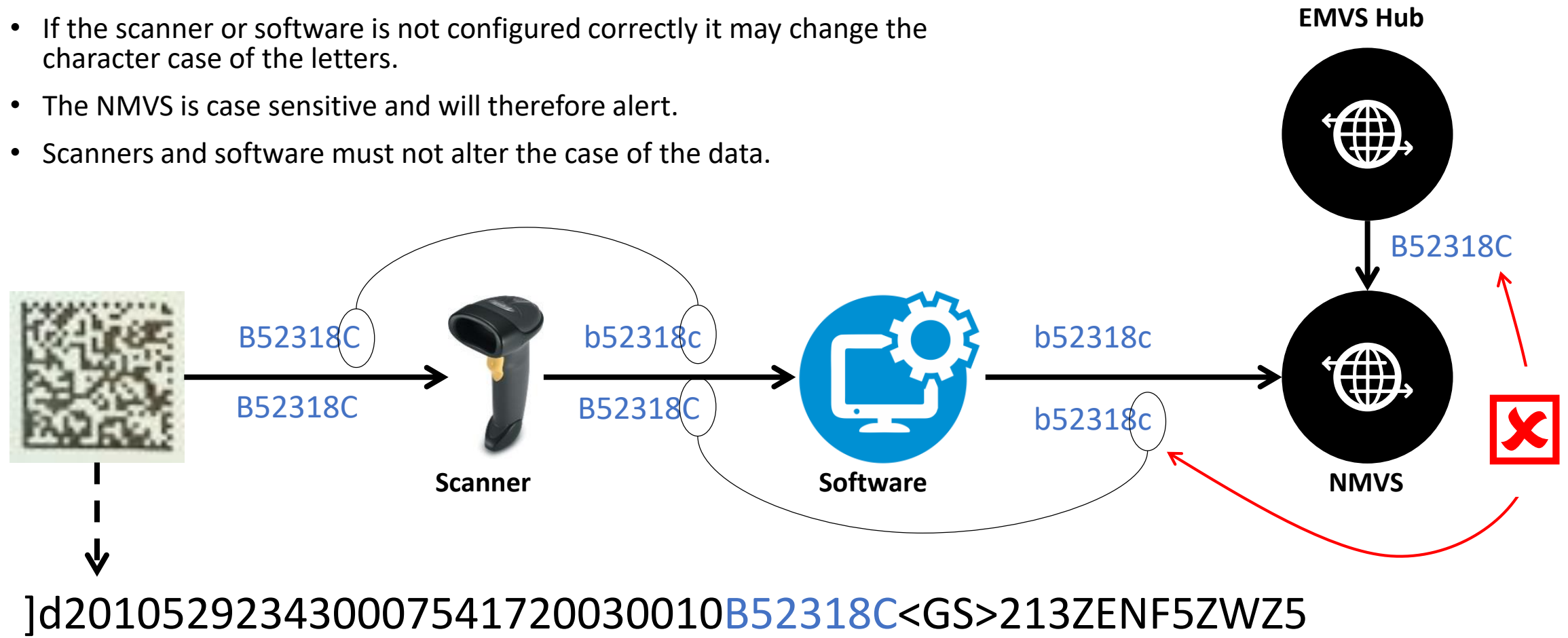
- In this example the DataMatrix is encoded using the GS1 standards
- The batch data is shown below in blue
- The Batch and Serial Number data have letters in upper case
- It is therefore important that this is not changed when scanned

]d201052923430007541720030010B52318C<GS>213ZENF5ZWZ5

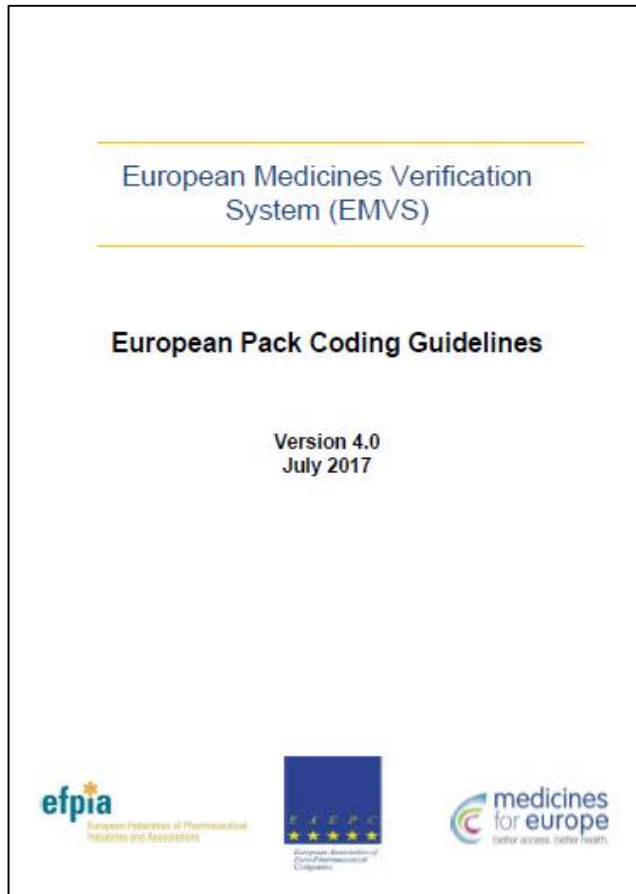
Case sensitivity

How the error is introduced by incorrect scanner and/ or software set up

- If the scanner or software is not configured correctly it may change the character case of the letters.
- The NMVS is case sensitive and will therefore alert.
- Scanners and software must not alter the case of the data.



The manufacturing associations in Europe agreed to follow international standards to encode



- The European Pack Coding Guidelines acknowledges that upper and lower case letters can be used, as per ISO and GS1 standards
- They further recommend that all upper or lower case are used in any specific barcode

2.2 The Serial Number

The serial number is preceded by the AI 21 and adheres to the GS1 specification where this field is a variable length (up to 20) alphanumeric field followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field).

It is recommended that three further modifications should be considered to aide consumer readability:

- The alphanumeric range shall include the digits 0-9 and the letters of the western alphabet but exclusion of the following letters: i, j, l, o, q and u. (I J L O Q U) might help avoid confusion with similarly shaped characters/numerics.
- The serial number character string should only contain either lower case or upper case letters, not a mixture.
- Use of the extended symbols, as defined by the complete GS1 specification and documented below, should ideally be avoided.

Data encoding order

How data is encoded

Order of data in the 2D Data Matrix Barcode



These numbers in red are called Application Identifiers (AI). They tell the scanning equipment what the next piece of data is e.g.

This tells the scanning equipment that the barcode is a 2D DataMatrix encoded with data in a GS1 format

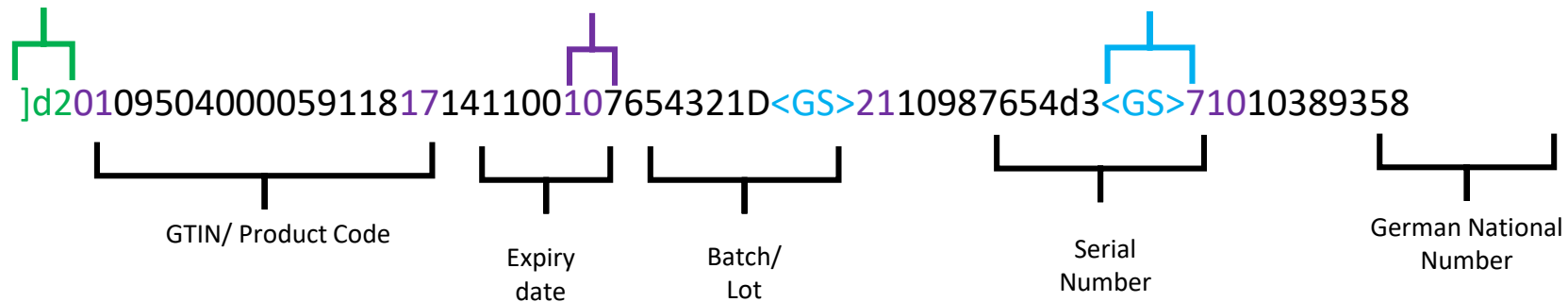
01 = GTIN/ Product Code
17 = Expiry Data
10 = Batch/Lot
21 = Serial Number
710 = German National Number

This separator tells the scanning equipment that the last piece of data has ended, a little like a full stop at the end of a sentence.

They are needed as some pieces of data can vary in length (variable length) e.g. the serial number can be up to 20 characters long

Without these separators the scanning equipment can not tell how long a variable length data item is.

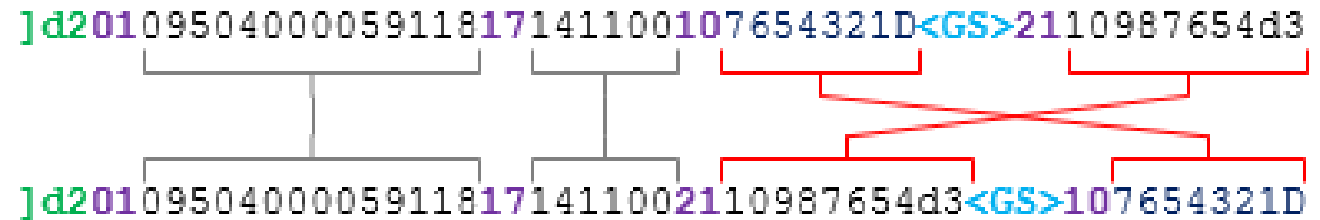
A separator is always followed by an Application Identifier to tell the scanning equipment what comes next.



What else should be considered when decoding

Other issues which are also overlooked when reading barcodes

Data can be encoded in various orders, decoding must use the syntax to establish where a specific field is in the data string and not expect the fields to always be in a specific location in the string or always the same length.



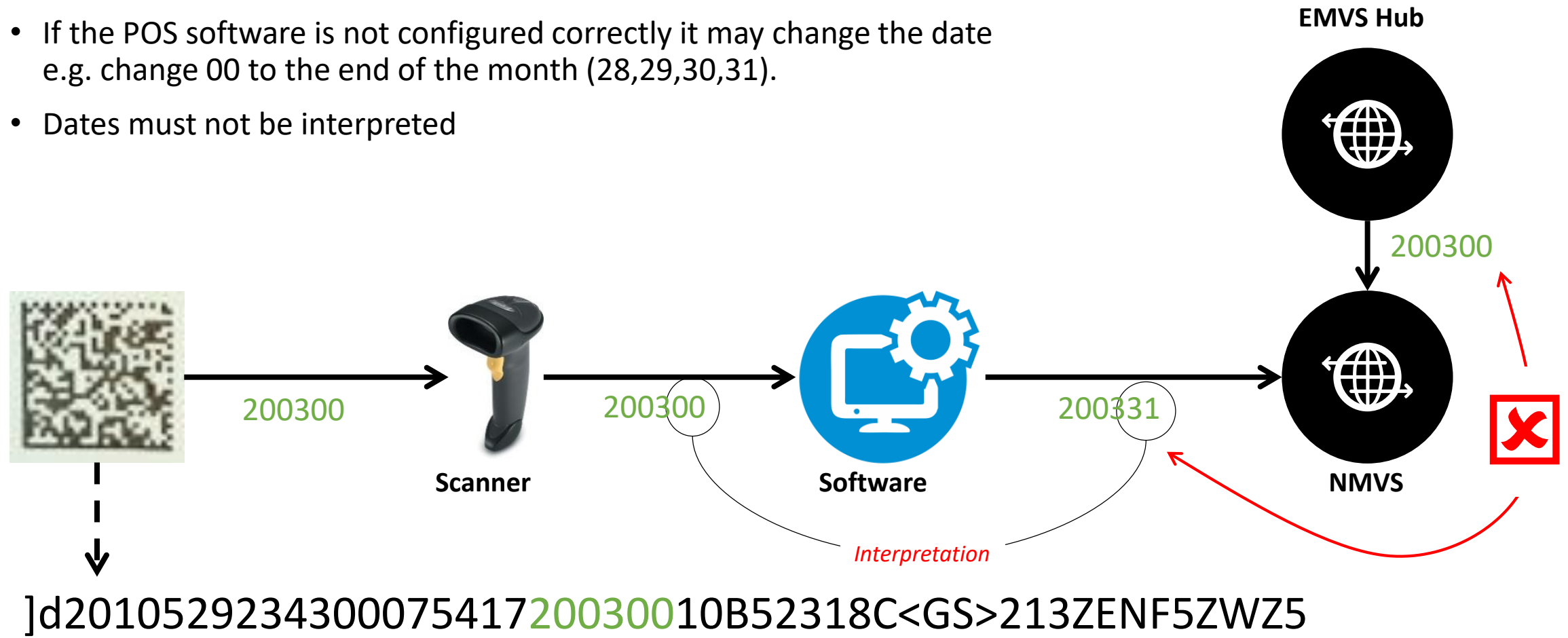
These two examples encode the same data, using the same syntax, however as the fields are in a different order the data strings are very different. An IT system must use the elements shown in blue and purple to identify the specific fields (Product Code, Expiry Date, etc).

Date interpretation

Date interpretation

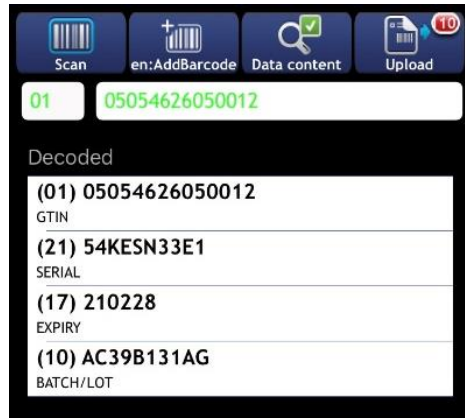
How the error is introduced by incorrect software configuration

- If the POS software is not configured correctly it may change the date e.g. change 00 to the end of the month (28,29,30,31).
- Dates must not be interpreted



Negative barcodes

Types of DataMatrix codes



- Some users have reported issues with negative datamatrix barcodes, however the test opposite showed there was no issues with the DataMatrix barcode on the pack
- Most modern scanners can be configured to read both positive and negative type of codes, even if they are set on a specific default when they are new
- As with character substituting, issues can be avoided if scanners and software set up correctly and tested before use



References

References

- EMVS – European Pack Coding Guidelines
- GS1 General Specifications
- ISO/IEC 646

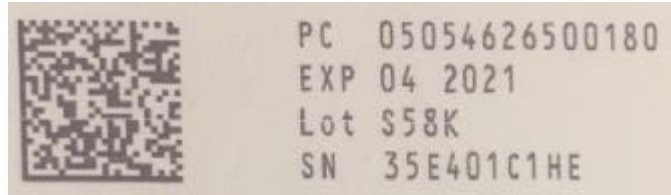
Spare slides

Character substituting

How to address this issue - Encoding

Manufacturers have followed International Standards to prevent encoding issues

Encode



There are several things which can be done to ensure that all manufacturers encoded data in the same way using global standards i.e.

1. Standard barcode - DataMatrix
2. Standard encoding method – GS1-128 syntax
3. Standard character set – GS1 character set

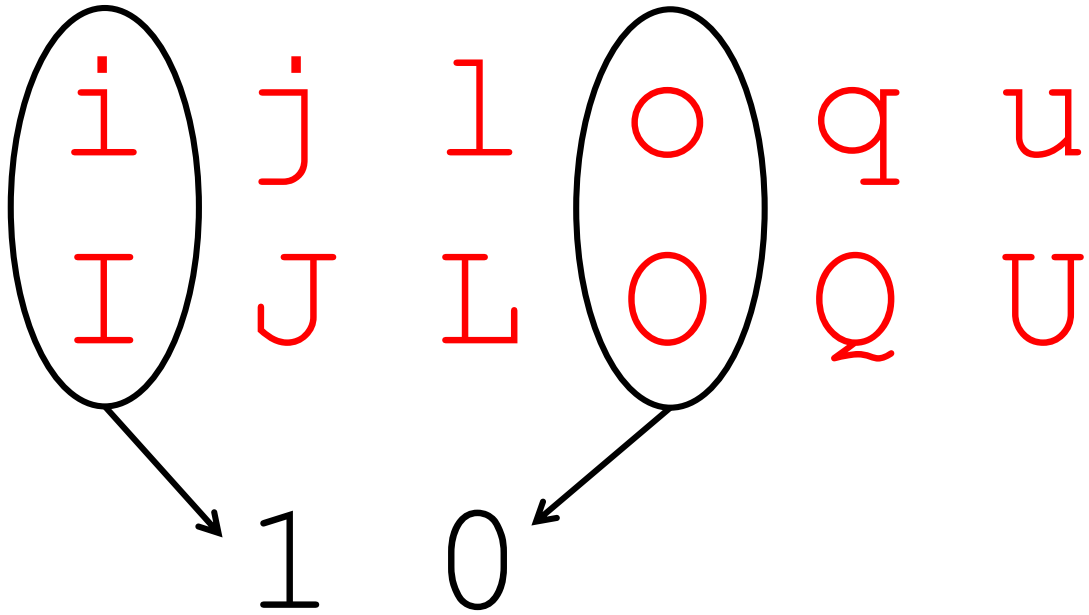
]d2010505462665001801721040010S58K<GS>2135E401C1HE

**The GS1 subset of
international standard
ISO/IEC 646**

Using global standards to encode ensures that every manufacturer works in the same way and the and there is no variation.

Some other restrictions

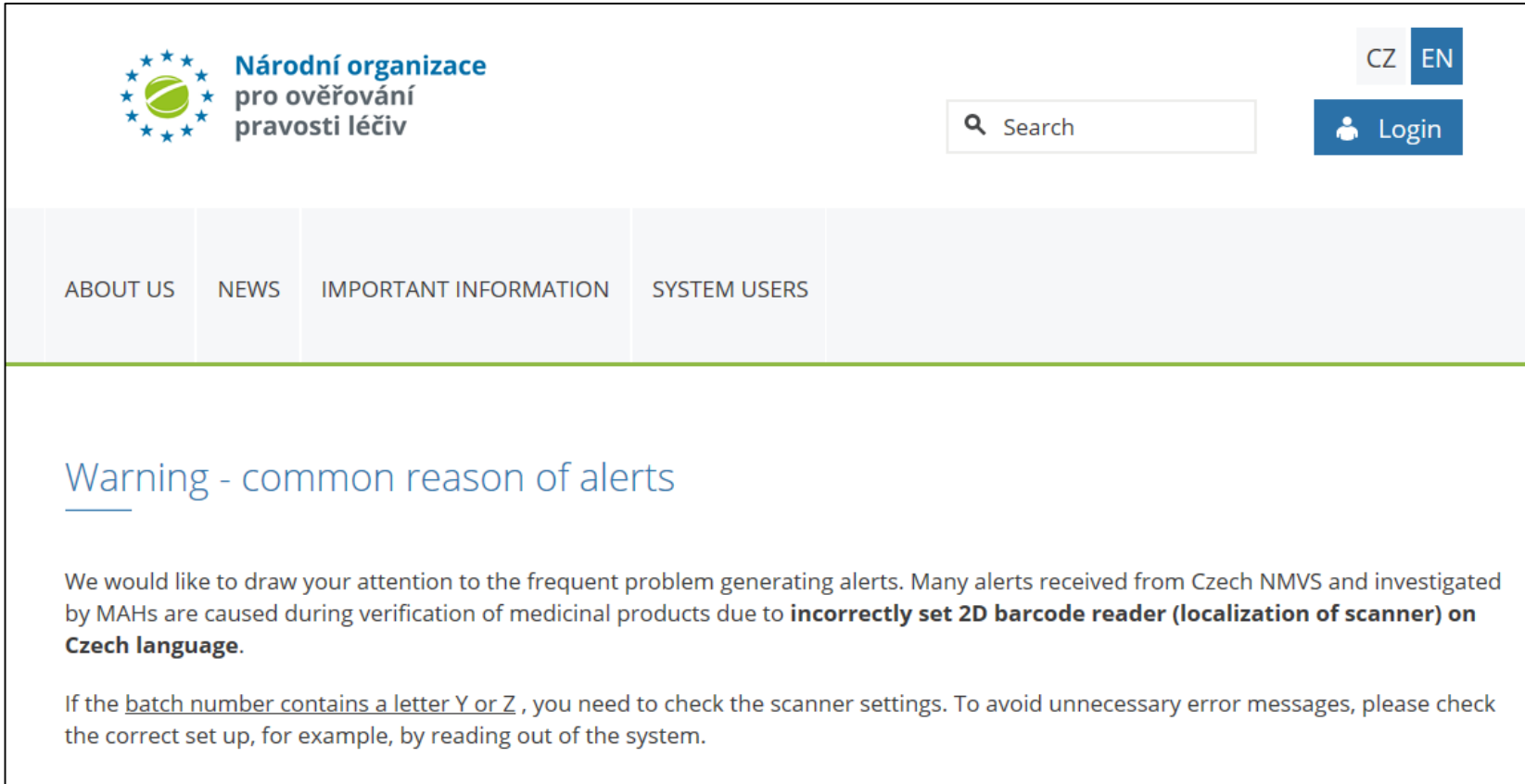
To help prevent human reading errors (not scanner set up issues)



- Whilst the GS1 standard uses 82 characters some of these look visually alike when read by a human
- It is therefore recommended that these are excluded from batch and serial numbers

Example of a decoding issue

This could happen when scanners are not set up correctly



The screenshot shows the website of the National Organization for Medication Verification (Národní organizace pro ověřování pravosti léčiv). The header includes the organization's logo, a search bar, and language selection options (CZ and EN). A navigation menu contains links for ABOUT US, NEWS, IMPORTANT INFORMATION, and SYSTEM USERS. The main content area features a warning titled "Warning - common reason of alerts".

Warning - common reason of alerts

We would like to draw your attention to the frequent problem generating alerts. Many alerts received from Czech NMVS and investigated by MAHs are caused during verification of medicinal products due to **incorrectly set 2D barcode reader (localization of scanner) on Czech language**.

If the batch number contains a letter Y or Z, you need to check the scanner settings. To avoid unnecessary error messages, please check the correct set up, for example, by reading out of the system.

- If scanners **are not set up correctly** they could pass incorrect data to the IT system which could then trigger an alert
- It is not possible for a MAH to distinguish between a real alert and an alert as a result of poor scanner configuration
- The users of scanners should be accountable to ensure they are set up correctly

Proposal

Proposal

Act now before it is too late

- We could offer a simple set of exemplar DataMatrix codes in a pdf file which could be used to test the scanner and software set up.
- These would also show the expected output so that a comparison could be performed
- The exemplars would be designed to cause poorly set up equipment to fail e.g.
 - The use of an upper case and lower case example
 - The use of positive and negative barcodes
 - The use of all characters allowed under the NMVS European Pack Coding guidelines
 - The encoding of the same data in various orders and also different field lengths
- Potentially partner with a scanning provider and/ or GS1 to produce this material with selected stakeholder experts
- Awareness of scanning issues could be raised through the appropriate industry associations as well as the EMVO and NMVO websites