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DATA MATRIX :
Technical Characteristics for Traceability

Project team members

This recommendation is the result of the work undertaken by the Project team comprising the following companies:

Companies:
ASTRAZENECA
BOIRON
JANSSEN CILAG
ROCHE
SANOFI AVENTIS

Wholesalers:
ALLIANCE HEALTHCARE
CERP FRANCE
CERP LORRAINE
CERP ROUEN
OCP REPARTITION
CSRP (Union)

Dispensing Chemist Trade Unions:
FSPF (The French federation of the pharmaceuticals unions)
UNPF (The French Union of the pharmacists)
USPO (Union of the pharmacists)

Introduction

In the French Official Journal of 16 March 2007, the AFSSAPS published a notice for the holders of marketing authorisation for medicinal products for human use and for head pharmacists working in the pharmaceutical establishments of manufacturers, importers, operators, consignees, wholesalers-dispatchers and wholesale distributors.

This notice covers the review of the coding and labelling systems relating to medicinal products for human use in order to support the compulsory information required for tracing medicinal products from the manufacturer to the patient.

The new outer packaging of the medicinal products will be clearly labelled with the CIP13 code, the batch number and expiry date. ECC 200 Data Matrix marking will be used. This is an international standard which enables the CIP13 code, batch number and expiry date to be acquired automatically when the label is scanned.

The following schedule defines the dates of publication of CIP7 and CIP13 switched codes as of 2007. Possible implementation of the first Data Matrix system on 1st January 2008, allocation of the first CIP13 codes only on 1st January 2009 and the deadline of 31st December 2010, date on which all medicinal products have to bear the new GS1 128 coding and ECC 200 Data Matrix marking.

Purpose of the recommendation

The CIP Board of Directors conferred the Pharmacy Traceability Implementation Project team the task of drafting a recommendation describing the technical characteristics of the Data Matrix system.

Data Matrix technical characteristics

The Data Matrix system selected is the ECC 200 Data Matrix as defined by the ISO/CEI 16022:2006 standard. This standard is available on the AFNOR site www.afnor.org.
This marking or bidirectional 2 dimensional (2D) symbol replaces the simplex linear barcode 39. It was selected as it is the smallest symbol that exists to date that can contain the largest data content.

Particular characteristics

- The Data Matrix system can encode up to 2,335 alphanumeric characters or 3,116 numeric characters.
- Data Matrix is arranged in either a square or rectangular pattern.
- It is made up of a frame and a matrix containing lines and columns.
- Each column and line contains modules in the form of a square or round symbol.
- These square or round modules are dark (1 bit) or light (0 bit). The colours can be reversed: light module on a dark background or dark module on a light background.
- The matrix size is selected according to the amount of data to be encoded but also according to the type of data (see table 1).
- ECC 200 Data Matrix differs from barcode 39 in its level of securisation in particular. ECC 200 uses the Reed-Solomon correction method which is widely implemented in various fields of industrial activity.
- All ECC 200 Data Matrix symbols can be recognised by the upper right corner module being light.

Table 1

Data Matrix Size Lines x Columns	Maximum number of Numeric characters	Maximum number of Alphanumeric characters
Square Data Matrixes		
18x18	36	25
20x20	44	31
22x22	60	43
24x24	72	52
26x26	88	64
32x32	124	91
Rectangular Data Matrixes		
12x36	44	31
16x36	64	46
16x48	98	72

Size determination

The size is defined by a number of rows and columns.
- Square Data Matrixes have sizes from 10x10 to 144x144.
- Rectangular Data Matrixes have sizes from 12x36 to 16x48.

The size will be selected according to the amount of data to be encoded and to whether the data is numeric or alphanumeric.
The sizes used for traceability are shown in table 1.

Important:

⚠
- Square Data Matrixes of sizes from 10x10 to 16x16 cannot be used to mark traceability as their capacity in terms of number of characters is too low. Those of sizes from 36x36 to 144x144 will not be used to mark traceability as their capacity in terms of number of characters is too high.
- Rectangular Data Matrixes with sizes from 8x18 to 12x26 cannot be used to mark traceability as their capacity in terms of number of characters is too low.

Restrictions with respect to the standard

There are two Data Matrix standards: ECC 000-140 and ECC 200.
ECC stands for Error Correction Codewords.
Only the ECC 200 is used as in the ECC200 the number of lines and columns are always the same. It can therefore be used for Reed-Solomon algorithm correction in the event of partial damage.
The data encoding protocol by default is the ECI 000003 (ECI = Extended Channel Interpretation) which describes the Latin alphabet according to the ISO 8859-1 standard (standard ASCII table).

Compression

The compression method selected is the default method in the GS1 standard, that is to say simple ASCII and extended ASCII.

Table 2

Compression method	Data to be encoded
Simple ASCII	ASCII characters 0 to 127
Extended ASCII	ASCII characters 128 to 255

⚠ Important: the other compression methods below present in the ISO 16022 standard are not used.

Table 3

Compression method	Data to be encoded
C40	Alphanumeric upper case
TEXT	Alphanumeric lower case
X12	ANSI X12
EDIFACT	ASCII characters 32 to 94
BASE 256	ASCII characters 0 to 255

Certain special characters can be used according to the GS1 128 standard.
AIM Inc. has selected «FNC1» to identify ECC 200 Data Matrix. FNC1 is equivalent to the ASCII 232 hexadecimal character. It is to be placed in the first character symbol position in the GS1 128.

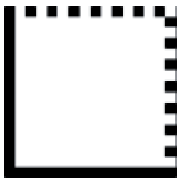
Table 4

Characters Hexa	Data or function
1 to 128	ASCII Data
129	Pad character (if the data does not take up all of the space)
130 to 229	Digit pair: 00 to 99
232	FNC1 character

Graphical Structure

Matrix boundary

The matrix's graphical boundary is represented by two adjacent sides which are solid dark lines forming an «L» (Finder Pattern) and another «L» on the opposite side as a dotted line (Alternating Pattern).



This boundary is used to identify the position of the marking and its absolute orientation. The boundary makes omni-directional scanning of Data Matrix possible. Scanning takes place independently of the position of the Data Matrix with respect to the scanner. Data Matrix can therefore be scanned in any direction.

This boundary is one module wide. It remains identical for a specific Data Matrix size regardless of the data encoded.

Data Matrix may sometimes be made up of several boundaries and several matrixes. Boundaries in this case are contiguous.

A quiet zone of at least one module wide is required on all 4 sides of the matrix in order to enable its identification. This quiet zone is of a smaller size than for simplex markings.

Data region placement in the matrix

Data Matrix modules are grouped into regions (codewords).

These regions are either data regions or Reed-Solomon blocks.

The Reed-Solomon blocks make data redundancy possible and are used to check consistency and to perform recalculations in the event of inconsistency.

The number of regions varies according to the size of the Data Matrix.

Comment: The number of numeric characters that can be encoded is twice as many as the number of data regions.

Encoding takes place in a single block regardless of the number of regions.

An example of region placement on an 8x8 matrix in a 10x10 Data Matrix boundary is shown in graph 1. Each region is identified by a digit.

Each region is placed in the matrix according to a pre-defined position and according to the specific size of each matrix. Each region is made up of 8 bits (bytes) represented by 8 squares. The 8 bits are either grouped (fields 2, 4, 6 and 8 in the graph) or fractioned (fields 1, 3, 4 and 7 in the graph).

Data region 1.1 Reed-Solomon block 4.3

Graph 1

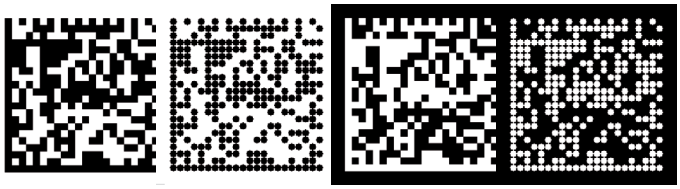
2.1	2.2	3.6	3.7	3.8	4.3	4.4	4.5
2.3	2.4	2.5	5.1	5.2	4.6	4.7	4.8
2.6	2.7	2.8	5.3	5.4	5.5	1.1	1.2
1.5	6.1	6.2	5.6	5.7	5.8	1.3	1.4
1.8	6.3	6.4	6.5	8.1	8.2	1.6	1.7
7.2	6.6	6.7	6.8	8.3	8.4	8.5	7.1
7.4	7.5	3.1	3.2	8.6	8.7	8.8	7.3
7.7	7.8	3.3	3.4	3.5	4.1	4.2	7.6

Table 5

Data Matrix Size Lines x Columns	Number of Data regions	Number of Reed-Solomon blocks	Maximum number of Numeric characters	Maximum number of alphanumeric characters
Square Data Matrixes				
18x18	18	14	36	25
20x20	22	18	44	31
22x22	30	20	60	43
24x24	36	24	72	52
26x26	44	28	88	64
32x32	62	36	124	91
Rectangular Data Matrixes				
12x36	22	18	44	31
16x36	32	24	64	46
16x48	49	28	98	72

Forms
The ECC 200 Data Matrix can be square or rectangular. In an identical module, the rectangular Data Matrix enables printing over an area that is longer vertically than horizontally and is therefore an ideal solution where there are space restrictions on the case (printing on the side for example).
However, the rectangular format which enables easy linear printing offers less possibilities than the square format where the amount of data to be marked is superior.

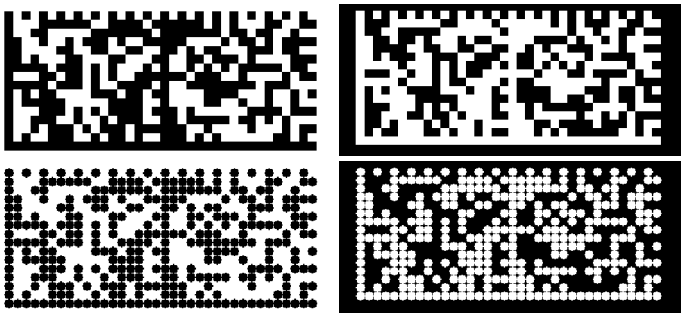
Examples
For a 22x22 matrix:



Printing dark symbols on a light background

Printing light symbols on a dark background

For a 12x36 matrix:



Printing dark symbols on a light background

Printing light symbols on a dark background

Not actual size.

Data structure

The data present in the Data Matrix for traceability is the CIP13 code, the expiry date and the batch number.
The data is preceded by a data identifier (Application Identifier AI). This is used to determine the precise nature of the data to follow.
The identifiers used for this recommendation are:
01 followed by the product code,
17 followed by the expiry date,
10 followed by the batch number.
To indicate to the scanner and to the associated software that GS1 128 syntax is present in the Data Matrix, the data must be preceded by « **FNC1** » of which the value is ASCII 232. This character is used by the 2D scanner but is not transmitted.

The data present behind each application identifier has a specific structure:

01 identifies the product code or GTIN (Global Trade Item Number) which is of fixed length. This product code must contain 14 characters. A zero «0» is therefore added before the CIP13. The addition of a zero does not modify the CIP13 control key.

17 identifies the expiry date which is of fixed length and must contain 6 characters in the YYMMDD format. If the day is not mentioned it must be replaced by « 00 » (zero zero). This date format is different from that in plain text that is MMYYYY.

10 identifies the batch number which is of variable length and contains from 1 to 20 characters and can be numeric or alphanumeric. It is preferable that the first character is different from zero to avoid any ambiguous interpretation. This batch number must be strictly identical to the number in plain text, with the same dashes, full stops etc.
As this batch number is of variable size from one medicinal product to another, it is recommended placing it in last position in the data. If this is not the case it is necessary to indicate the end of the batch number by a group separator character such as « GS », of which the value is ASCII 29. This character makes it possible to close data fields of variable length.

Example
FNC1010340093000012017YYMMDD10A11111

The parenthesis AI must not be bounded during data coding in Data Matrix in order to observe GS1 128 syntax.
The parentheses are only used for plain text printing to make human readable interpretation easier.
(01)03400930000120(17)YYMMDD(10)A11111

The information present in Data Matrix must be strictly identical to the information in plain text and to the dematerialised information transmitted by EDI.
Other data identifiers exist in the standard and could be added if they are useful for mentioning other data in Data Matrix.

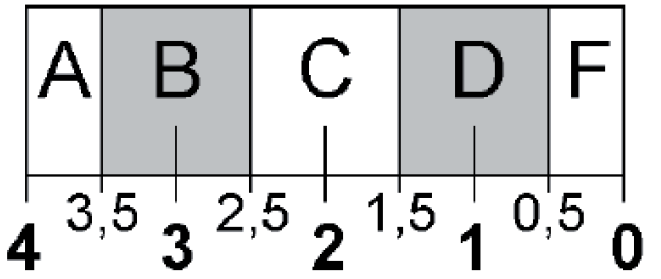
Data Matrix Marking

Print quality

The technical printing specifications can be found in the « AIM International Data Matrix Specification » available on the AIM Inc site (Association for automatic Identification and Mobility) at the following address http://www.aimglobal.org.
The reference document is entitled:
(11/96) ANSI/AIM BC11 International Symbology Specification – Data Matrix

The ECC 200 Data Matrix has the advantage of being able to print using standard barcode printing technology such as inkjet, laser and thermal transfer.
Each type of technology has advantages and disadvantages.
The standard used for print quality testing is the **ISO 15415 1.5 06 / 670** « Bar code print quality test specification 2D symbols ». This standard is available on the AFNOR site www.afnor.org.
The minimum recommended print quality is **grade C**, according to the ISO 15415 standard.
The printed surface must enable sufficient contrast between the modules and the background. Marking quality will depend on the homogeneity of the surface but also on the optimisation of the marking means selected.

ISO 15415 Grades - Details
The grades are based on 7 criteria. Each of these parameters is evaluated by a score determining the level of compliance.
The final 2D marking grade will be equal to the lowest grade among the seven criteria.
A, B, C: grades in descending order and ISO-compliant;
D: insufficient grade due to significant deviation;
F: specific grade with unacceptable deviation with respect to the standard.



Grade level

Graded criteria are:

- Marking contrast (Symbol contrast)
  Measures the difference in reflectance between the light areas and dark areas on the marking. Reflectance is the level of reflection of light on a given surface.


(1)

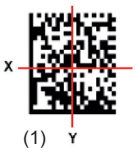
- Damage to the boundary and quiet zone
  (Fixed pattern damage)
  Measures the damage to the external marking boundary and to the quiet zone.


(1)

- Inhomogeneity (Modulation)
  Measures the variation in reflectance or in the size of the light and dark modules.

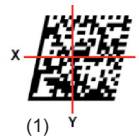

(1)

- Axial non-uniformity
  Measures the deviation of the marking following one of the main axes (x or y).



(1)

- Grid non-uniformity
  Measures the most significant trapezoidal deviation with respect to the axes of the theoretical grid.



(1)

- Evaluation of available Reed-Solomon calculation headers
  (Unused error correction)
  Measures the unused error correction level.


(1)

The non-graded criterion is:

- Print growth
  Indicates print growth of the actual size compared to the theoretical size of the light and dark areas.

Final print growth takes all of the results along with the measuring conditions: type of lighting, resolution (aperture) for module measurement and the final grade.


(1)
Overprinting


(1)
Under printing

Tips

- Check with the supplier that the printer is compliant with the Data Matrix ISO/CEI 16022 standard.
- Check the software's ability to support GS1 128 syntax with AI and of course to encode ECC 200 Data Matrix.
- Check transcription of FNC1 still present in the marking and of GS if it was used.

Printing technique

To remain in keeping with the legislation it is necessary to ensure that the surface to be marked is suitable for printing.
Three points are to be taken into account in particular:

- compatibility of the surface with the type of marking,
- verification through testing that rubbing does not damage the marking,
- verification through testing of the legibility of the marking in certain damp conditions.

Using the same print quality for information redundancy the Data Matrix is more legible than linear marking.

(1) © Microscan

Location

The Data Matrix contains information concerning traceability and must be present on one of the sides of the secondary packaging.
It must be placed preferably on a flat surface.
It should not be placed on the underside of the packaging to make scanning by the robot easier, except if this contradicts the previous recommendation.
If the Data Matrix is placed on a rounded surface, it must be placed so as to minimize the field depth required for correct scanning. Rectangular Data Matrices are recommended in this case.
To facilitate the pharmacist's work, it must be placed where possible on the same side as that of the current label to enable all information concerning traceability and reimbursement to be scanned at the same time.
The order in which the Data Matrix is placed with respect to the label is not important.
The two symbols must be spaced out by at least one Data Matrix module but ideally they should be spaced out by 4 modules.
The surface on which the two symbols are located must be inferior to the scanner scanning area.

Dimension

Module dimension

For easy scanning by various equipment types, the module must be 0.3 mm or greater. Reducing the module size by at least 0.255 mm would lead to a loss in legibility. The maximum size authorised for the module is 0.615 mm. See GS1 General Specifications Sections 2.7.6.2, 5.4 and 5.6.3.5.

Data Matrix Dimension

The Data Matrix dimension is defined by:
- The matrix selected (See table 1),
- The module dimension,
- By the quiet zone, shown as an area identical to the print background. This field which contains no marking or colour variation is of a minimum width of the size of a module; an ideal margin is 4 modules wide.

Square Data Matrix
According to table 1, for a 0.3 mm module:
- For an 18x18 Data Matrix, the size of the Data Matrix is 7.8 x 7.8 mm including the quiet zone.
- For a 32x32 Data Matrix, the size of the Data Matrix is 12 x 12 mm, including the quiet zone.

Rectangular Data Matrix
According to table 1, for a 0.3mm module:
- For a 12x36 Data Matrix, the minimum size of the Data Matrix is 6 x 13.2 mm, including the quiet zone.
- For a 16x48 Data Matrix, the maximum size of the rectangular Data Matrix is 7.2 x 16.8 mm, including the quiet zone.

Data Matrix Checking

Specific devices known as verifiers are used to evaluate all quality criteria.
The standard for barcode verifier conformance specifications is the **ISO 15426-2:2006** « Bar code verifier conformance specification ». Section 6.3.2 covers Data Matrix.
This standard is available on the AFNOR site www.afnor.org.
Simply scanning Data Matrix is not sufficient. The legibility test with a given scanner provides information concerning the legibility of the marking under specific conditions (same tool and scanning conditions). It in no way guarantees legibility for any other scanner in other conditions.
Certain scanners have a verification function but it cannot be used to measure all quality criteria.
Up until now, barcode 39 was often printed outside the production line by a printer. For Data Matrix which contains variable data and which is printed on the packing line, additional checks are required.
If traceability data cannot be scanned the pharmacist would be required to manually enter from 20 to 40 characters per case to ensure traceability.
Compliance checks covered by international standards are therefore a valuable asset for guaranteeing legibility in pharmacies. The points to be improved are indicated where necessary.
The ISO criteria covering the verifiers are as follows:
- ECC200 model check
- Data Matrix format and size
- quiet zone quality
- marking contrast
- dot homogeneity
- axial uniformity
- grid uniformity
- print uniformity
- unused error correction level.

ISO 15426-2 certified verifiers provide a full guarantee for Data Matrix print quality.

Data Matrix Scanning

A CCD camera or imaging reader is used to scan ECC 200 Data Matrix. It scans the image and then records it. This image will then be decoded by the scanner's software to determine its nature and content. This will transfer the character set present in Data Matrix, including the AIs, to the pharmacy's IT system. The system will then analyse the data content received and will manage it accordingly.

Integration of the data in the user's IT system must always be carried out when the Application Identifiers have been read (AI).

Example
0103400930000012017YYMMDD10A11111

Is read as
01 = 0 + CIP13 code
17 = expiry date
10 = batch number

Scanners must not have any « dead zones », that is to say, scanning must always be possible regardless of the distance between the scanner and the packaging.

Scanners must be able to detect the symbols automatically.

Summary

In the French Official Journal of 16 March 2007, the AFSSAPS published a notice for distributors of medicinal products for human use (manufacturers, importers, operators, consignees, wholesalers, dispatchers and wholesale distributors) covering the review of the coding and labelling systems to support the compulsory information required for tracing medicinal products from the manufacturer to the patient.
The following will be made compulsory within the healthcare system by the 31st of December 2010:

- 13-character coding to replace 7-character coding, the CIP13 code featuring along with the batch number and expiry date.
- Simplex linear barcode 39 marking to be replaced by the bidirectional, 2-dimensional ECC200 Data Matrix marking. Data Matrix is an international standard and it is the smallest symbol existing to date that is able to contain the largest data content.

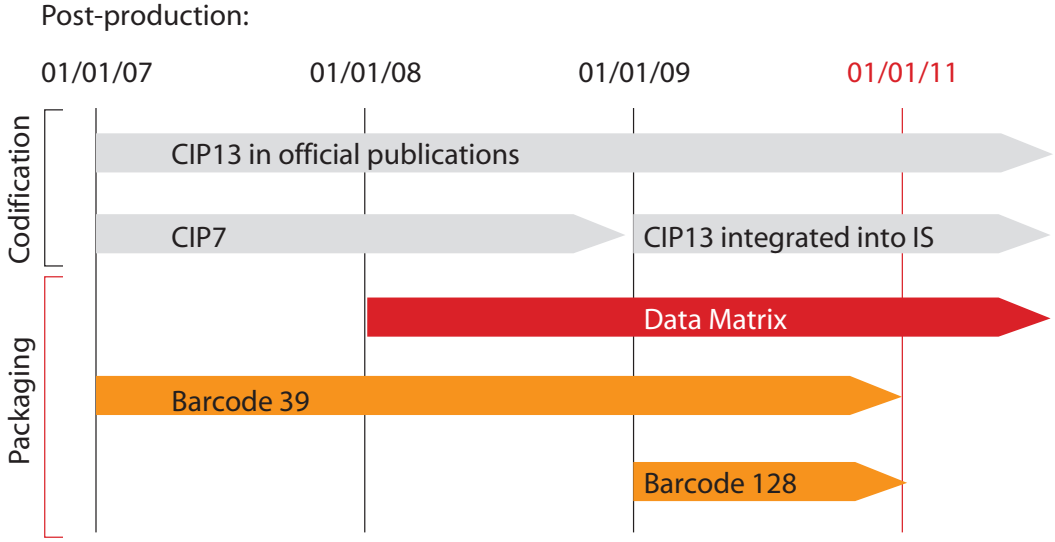
According to the schedule outlined by the authorities, the first Data Matrix markings are set to appear on the outside packaging of medicinal products as of 1st January 2008.

Created by the players in the distribution chain, this reference document describes the technical characteristics of Data Matrix which are essential in implementing the traceability of medicinal products for human use: size, compression, graphical structure (matrix boundary, area layout, and shapes), data structure, printing (print quality, printing techniques, position, and dimension), verification and scanning.

KEY WORDS

Traceability – Marking – Medicinal products for human use – Data Matrix – Technical Characteristics – Coding – Upgrade – CIP Code – MA Code – Printing – Verification – Scanning – Batch – Expiry Date – CIP13

Implementation schedule



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