GS1 Germany

Identification of Medicines in Germany

NTIN Guideline for use in the securPharm pilot project

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Version 1.2

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GS1 Germany supports companies from all sectors in the adoption and practical implementation of modern communication and process standards, in order to improve the efficiency of their business processes. Within Germany, the company is responsible for the maintenance and continued development of the GS1 article identification system GTIN for globally unique identification, which in turn serves as the basis for bar codes. Moreover, GS1 Germany supports the application of new technologies for fully automatic object identification (EPC/RFID) and offers customer-orientated solutions (ECR - Efficient Consumer Response).

Based in Cologne, the private sector company belongs to the international network ”Global Standards One“ (GS1) as one of the largest of more than 100 national GS1 organisations worldwide. The German Markenverband and the EHI Retail Institute hold equal shares in GS1 Germany.

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About this paper

In July 2011, an EU directive was adopted which provides that counterfeited medicines must not enter the legal supply chain. The new policy updates the existing rules and introduces security features that have to be affixed to the packaging to ensure the authenticity and the identification of each package. These security features have to be laid down by the European Commission until 2014.

In Germany, the pharmaceutical associations (ABDA, BAH, BPI, PHAGRO and vfa) jointly established the initiative securPharm eV. This initiative developed a solution concept for anticounterfeiting of drugs. It will be tested in a pilot project in 2013.

In the pilot, pharmaceutical packaging will be marked by the manufacturer with the product identification number and serial number provided in a data matrix. The pharmacies scan this data matrix and verify the authenticity of the packaging via a protected database.

A proven solution for use in the project is based on GS1. In order to fulfill the demand of the German market, a NTIN (National Trade Item Number) is used for product identification. This embeds the PZN into an international identification number using a GS1 Germany prefix.

Cologne, May 2012

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1 Global Trade Item Number (GTIN)

The basic option for the identification of any medicinal products is the use of a Global Trade Item Number (GTIN) by the manufacturer or brand owner[1] of the product.

The manufacturer is responsible for the allocation of the GTIN. Each GTIN is based on the GS1 company prefix that is assigned by GS1 Germany in connection with a GLN (Global Location Number).

The GTIN is structured as follows:

Global Trade Item Numbers (GTIN)		
Company Prefix	Individual item number	Check Digit
4 0 1 2 3 4 5	0 0 0 2 5	2
4 2 1 2 3 4 5 6	0 0 2 5	8
4 3 1 2 3 4 5 6 7	0 2 5	8

Fig. 1: Global Trade Item Number

- Company prefix:

The 7- to 9 digit company prefix is derived from the Global Location Number (GLN) of the manufacturer / brand owner. It ensures the uniqueness and unambiguity of the GTIN. The length of the company prefix determines the capacity of available numbers (GTINs). 2

- Individual item number:

On the basis of the company prefix, the manufacturer append an individual item number number up to five digits at its own discretion. In a 7-digit company prefix, any combination of five digit number "00000" and "99999" can be formed. Using such a company prefix, more than 100.000 unique GTIN numbers can be generated.

[1] In the following solely referred to as manufacturer

[2] If the 7-digit company prefix is not sufficient, than the manufacturer can ask GS1 Germany for another GLN.

- Check digit:

The 13th position of the GTIN is a check digit. It is calculated over the preceding 12 digits. The check digit of the GLN type 2 must not be taken over, but a new check digit must be calculated for each GTIN.

2 National Trade Item Number (NTIN)

In Germany, pharmaceuticals are identified with the Pharmazentralnummer (PZN). The PZN is issued centrally by the IFA GmbH which is the registry for all medicinal products sold in pharmacies. The PZN is an 8-digit number that is encoded in code 39.

Against the background of the EU Directive which is for the safety from counterfeit medicines and following the international developments, the responsible pharmaceutical associations and GS1 Germany have jointly decided to integrate the PZN in the GTIN format. The “new” number is the so-called “National Trade Item number”.

The PZN with its 8 digits is integrated into the structure of the GTIN. GS1 Germany provides the industry with the 4-digit prefix 4150. Thus, the NTIN has the following structure:

NTIN for medicines in Germany*		
GS1 Germany Prefix	8 – digit PZN	Check digit
4150	12345678	2

Fig. 2: Structure of the NTIN in Germany

The part of the GTIN which is called individual item number is filled with the 8-digit PZN. The NTIN is used exclusively for the identification of individual products.

* If the PZN has only 7 digits use “0” before the 7-digit PZN.

3 Data elements

The EU pharmaceutical package provides not only the unambiguious identification of medicinal products, but also the identification of each pharmaceutical package with a serial number. Furthermore, the secondary information which is the lot number and the expiration date has to be bar coded on each package.

3.1 The GS1 Application Identifier

The GS1 application identifier system is used in GS1 codes like GS1 DataMatrix. It ensures the accuracy of reading and processing the data encoded throughout the supply chain. It is based on an exact definition of all relevant data items (such as serial number, expiration date), the determination of their sizes and the assignment of qualifying data identifiers (AI).

The application identifiers indicate the nature of the information in the code, and the format in which it is encoded.

AI	Coded Data Content	Format*
00	SSCC	n2 + n18
01	GTIN	n2 + n14
10	Batch Number	n2 + an..20
11	Production Date (YYMMTT)	n2 + n6
13	Packaging Date (YYMMTT)	n2 + n6
15	Best Before Date (YYMMTT)	n2 + n6
17	Expiry Date (YYMMTT)	n2 + n6
20	Product Variant	n2 + n2
21	Serial Number	n2 + an..20
30	Amount	n2 + n..8
310**	Net weight in Kilogram	n4 + n6
315**	Net volume in Liters	n4 + n6
400	Order Number of Receiver	n3 + an..30
410	„Ship To“, GLN of Receiver	n3 + n13

Fig. 3: Extract of existing application identifiers (AI)

The GS1 application identifiers are used in the GS1 codes whenever there is a need to encode several pieces of information. Thus, they are used in the GS1 DataMatrix symbology. Combining data identifiers with a protected symbology ensures that the GS1 DataMatrix code is not only read but also interpreted accurately by each partner of the supply chain. The high risk of data collision due to incorrectly interpreted data is excluded. Especially in sensitive product areas such as healthcare this is an important advantage.

3.1.1 Encoding of GTIN and NTIN

Both, GTIN and NTIN are data elements of pre-defined length, namely 14 numeric digits. Therefore, they are preceded by a leading zero in the first position of the 13-digit GTIN or NTIN. Application identifier "01" is used in the GS1 DataMatrix.

Example: NTIN (01)04150123456782

3.1.2 Encoding of batch numbers

The batch number is a number formed by the manufacturer and assigned to a specific production. It is encoded in GS1 DataMatrix by using application identifier "10". It is not of pre-defined length, namely up to 20 alpha numeric digits. Therefore, it must be followed by a field seperator when concatenating more application identifiers. The FNC1 character acts as field seperator. It is not required after the last AI and last data encoded in the symbol independent of whether the field is pre-defined of not.

Example: Batch No. (10)ABC1234567

3.1.3 Encoding of serial numbers

The serial number is also assigned by the manufacturers. The pharmaceutical associations have agreed that the serial number has to be assigned randomly. The serial number is encoded with application identifier "21". Like the lot number, the serial number is also not of pre-defined length but up to 20 characters alphanumeric. Therefore, it must be followed by the FNC1 character when concatenating more application identifiers. It is not required after the last AI and last data encoded in the symbol independent of wether the field is pre-defined of not.

Example: Serial No. (21)123456789012

3.1.4 Encoding of expiry dates

The expiry date is also required coded on the drug package. Application identifier "17" indicates the expriry date in the format YYMMDD (e.g. 120401 for the 1st April 2012). If it is not necessary to specify the day, the field “DD” must be filled with two zeros. The expiry date is of pre-defined length. Therefore, no field seperator (FNC1) is required.

Example: Exp. (17)151000

4 Symbology and human readable interpretation

4.1 GS1 DataMatrix symbology

Data matrix is a two-dimensional matrix symbology that has been developed in the mid 90s. The technical specifications are defined in the ISO standard 16022. GS1 DataMatrix as subset of data matrix is available since 2004. Similar to the GS1-128 bar code, the GS1 DataMatrix encodes a FNC1 character in the first position. Thus, the same accuracy in reading and processing GS1 DataMatrix is achieved as with all other GS1 symbologies.

The advantage of GS1 DataMatrix is that much more information can be encoded in a very small space. It is, however, the basic rule that as much information as necessary but as little as possible should be encoded. As GS1 DataMatrix is a 2D code, appropriate reading systems are required. Those are often referred to as image scanners. The advantage of 2D scanners is that they can be used universally because they can decode both linear and 2D codes.

When using GS1 DataMatrix, the application identifiers must be used.

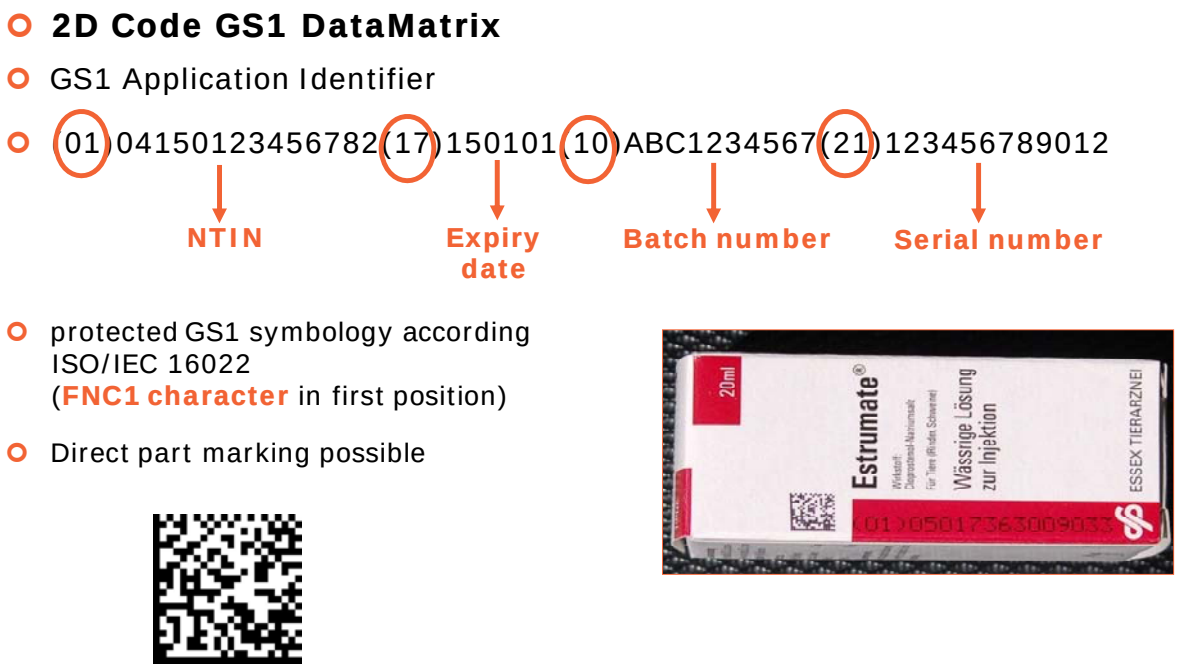
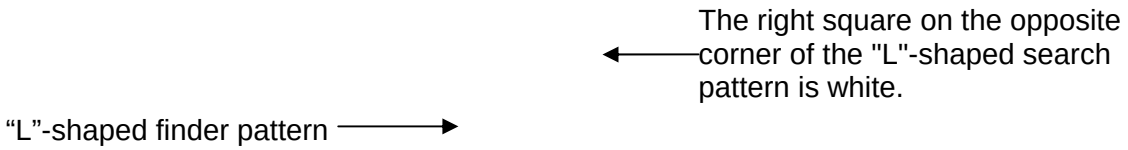


Fig. 4: GS1 DataMatrix

4.1.1 Technical features of GS1 DataMatrix

The GS1 DataMatrix code has the following typical structure:



- The "L"-shaped finder pattern has a width of one module.
- A quiet zone is required on each side. The quiet zone is one module. This area may not be printed.
- ECC 200 symbols can always be distinguished from other, older versions of the data matrix since the opposite corner of the corner of the "L"-shaped search pattern is empty (a null module) or white in a printed symbol.
- For square GS1 DataMatrix symbols, the number of rows equals the number of columns. Depending on the data requirements, the size of the symbols varies from 10 rows by 10 columns (10 x 10) up to 144 rows by 144 columns (144 x 144) (including search pattern, but with no quiet zone).
- A module is 1X in hight and 1X in depth. Data representation: A dark element is a binary one, a light one is a binary zero (or a light module is a binary one and a dark module is a binary zero for symbols with reverse reflection).
- ECC 200 (ECC = Error Checking and Correction) uses the Reed-Solomon error correction algorithm.
- The FNC1 character in the first position (and in fifth position in multi-codes) in the GS1 DataMatrix announces the use of the GS1 application identifiers, thus ensuring compatibility with the GS1 system. It corresponds to the ASCII value of 232. If the FNC1 character is used elsewhere, it is rated as group seperator and transmitted as <GS> (ASCII value 29).
- Character sets:
  - Value 0 - 127 following ISO/IEC 646, i. e. all 128 ASCII characters.
  - Value 128 - 255 following ISO/IEC 8859-1 (extended ASCII).
- Amount of data in one symbol
  - Alphanumeric data: up to 2335 characters

  - Byte data: 1556 characters
  - Numerical data: 3116 figures

- Large, square ECC 200 symbols (at least 32 x 32 modules) have finder patterns to distinguish the individual blocks of data (multi-code).
- Code type: Matrix
- Orientation independence (requires two-dimensional image scanner).
- Additional characteristics of the GS1 DataMatrix:
  - Reverse (inverse) Reflection: symbols can be read either dark on light or light to dark.
  - Rectangular symbols: Six symbol formats are specified for rectangular shapes.
  - Extended Channel Interpretation (ECI): This option allows to encrypt data from other alphabets in the data matrix.

4.1.2 Symbol structure

A GS1 DataMatrix symbol consists of at least one matrix (finder pattern and clock-track) and variable cells (content code).

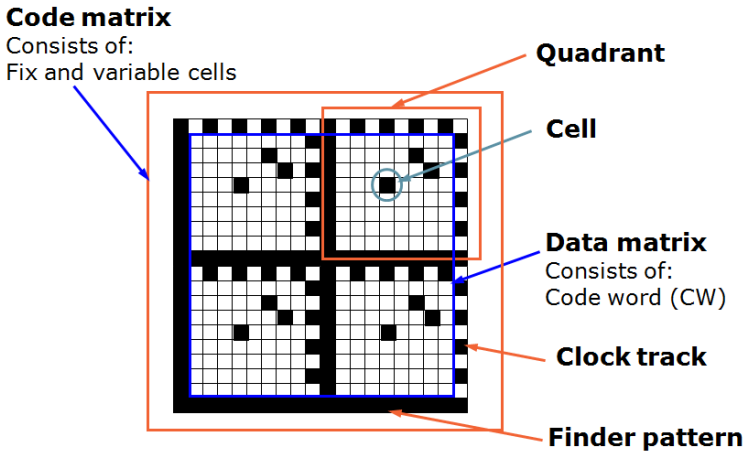
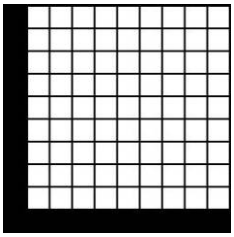


Fig. 5: Basis elements of a GS1 DataMatrix code

4.1.3 Finder pattern and clock-track

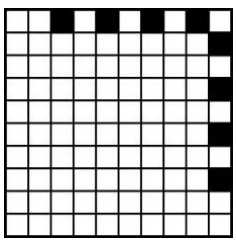


Tasks of the finder pattern:

- rapid detection of the code
- Auto discrimination
- Location and size determination
- detection of distortion.

Object of the clock cells:

- basis for creating a reference grid for checking the validity of a cell



4.1.4 Code structure: Cell

Every single cell in a GS1 DataMatrix is built square whereby the cell size X (both in width and in height) corresponds the module width X.

A cell can be either a binary 1(in this case it is black or filled) or a binary 0 (in which case it is white or blank). The opposite applies for symbols with reversed (inverted) reflection.

Figure 6 shows the allowable size tolerances of cells in data matrix symbols.

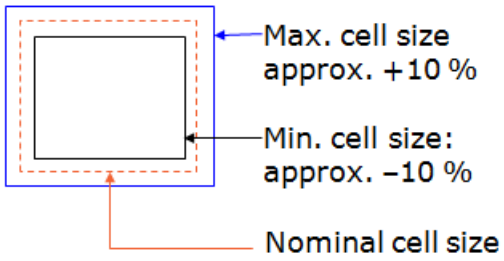


Fig. 6: Admissible tolerances related to cell size

4.1.5 Square and rectangular format

The GS1 DataMatrix can be represented in either rectangular or square format. The square format is used because it provides a greater number of different sizes and the amount of data encoded is lager. The largest rectangular symbol can encode 98 digits, while in the largest square 3116 numbers can be encoded.

Fig. 7: Rectangular and square GS1 DataMatrix symbols (magnified symbols). The same data is encoded.

4.1.6 Symbol sizes

Depending on the amount of data the GS1 DataMatrix symbols vary in their size. The square format has GS1 DataMatrix symbols in 24 different sizes from 10 x 10 modules up to 144 x 144 modules (without quiet zone). For the rectangular format, there are six different sizes from 8 x 18 modules up to 16 x 48 modules (without quiet zone). GS1 DataMatrix symbols with sizes of 52 x 52 or more modules have 2 to 10 blocks of Reed-Solomon error correction code words merging one into another

Square symbols:
- 24 matrix sizes
- from 10 x 10 up to 144 x 144 cells*

1 Quadrant: up to 26 x 26
4 Quadrant: up to 52 x 52
16 Quadrant: up to 104 x 104
36 Quadrant: up to 144 x144

Rectangular symbols:
- 6 Matrix sizes
- from 8 x 18 up to 16 x 48 Zellen*

1 rectangle: up to 16 x 48

* Without quiet zone

Fig. 8: Data Matrix ECC 200 – Code sizes

The two tables below show an extract of possible matrix sizes and their data capacity.

Symbol size*		Data area			Total Code words		Reed-Solomon Block		Mer-ging blocks	Data capacity			Defect	Max. correctionr
Row	Column	Size	No.	Matrix size	Data	Defect	Data	Defect		Num. cap.	Alphan. cap.	Byte cap.	corr. Over-head %	Code word Deftct/ex-tinction
10	10	8x8	1	8x8	3	5	3	5	1	6	3	1	62,5	2/0
12	12	10x10	1	10x10	5	7	5	7	1	10	6	3	58,3	3/0
14	14	12x12	1	12x12	8	10	8	10	1	16	10	6	55,6	5/7
16	16	14x14	1	14x14	12	12	12	12	1	24	16	10	50	6/9
18	18	16x16	1	16x16	18	14	18	14	1	36	25	16	43,8	7/11
20	20	18x18	1	18x18	22	18	22	18	1	44	31	20	45	9/15
22	22	20x20	1	20x20	30	20	30	20	1	60	43	28	40	10/17

		20												
24	24	22x22	1	22x22	36	24	36	24	1	72	52	34	40	12/21
26	26	24x24	1	24x24	44	28	44	28	1	88	64	42	38,9	14/25

a) Characteristics of square symbols (extract)

Symbol size*		Data area			Total		Reed-Solomon		Merging blocks	Data capacity			Defect	Max. Correction
					Code word		Block						corr.	Code word
Row	Column	Size	No.	Matrix size	Data	Defect	Data	Defect		Num. cap.	Alphan. cap.	Byte cap.	Over-head %	Defect/ extinction
8	18	6x16	1	6x16	5	7	5	7	1	10	6	3	58,3	3/+
8	32	6x14	2	6x28	10	11	10	11	1	20	13	8	52,4	5/+
12	26	10x24	1	10x24	16	14	16	14	1	32	22	14	46,7	7/11
12	36	10x16	2	10x32	22	18	22	18	1	44	31	20	45,0	9/15
16	36	14x16	2	14x32	32	24	32	24	1	64	46	30	42,9	12/21
16	48	14x22	2	14x44	49	28	49	28	1	98	72	47	36,4	14/25

b) Characteristics of rectangular symbols (Extract)

* Size of the symbols without quiet zone

4.1.7 Module width and height (X)

The value of X specifies both the module width and the module height. This value must remain the same for the entire symbol. The determination of the module width and height (X) is done within the application guidelines. The X-module is 0.255 for use in healthcare sector.

4.1.8 Human Readable Interpretation

In principle, the primary identification (e.g. GTIN) should always be written in human readable below the symbol, while additional information is requested above. The signs should be clearly legible (such as OCR-B font according to ISO 1073-2) and placed nearby the symbol.

Application identifier should be readily apparent to facilitate a manual input. Therefore, application identifiers should be written in parentheses.

Note: The parentheses are not part of the data and are not encoded in the code.

4 Symbology and human readable interpretation

If large amounts of data are encoded in the GS1 DataMatrix, a human readable interpretation of all data elements is due to space reasons often not possible. Even if space is available, a human readable interpretation of all the information for a manual input is often not useful. In these cases, a portion of the data may be omitted. However, the primary identification must be printed according to GS1 specifications.

More detailed rules for the human readable interpretation can be found in each application recommendation. For the pilot project, securPharm formulates separate rules which can differ in parts from the above mentioned GS1 specifications.

They are a set of general rules, such as the determination that serial and product number will not be applied in human readable on the packages in order to avoid errors when typing in the number manually.

securPharm works on the relevant documents to support the users. Those are expected to be available within the next four weeks.

4.1.9 Data transmission and symbology identifiers

GS1 DataMatrix symbology uses the identifier "]d2" for GS1 System compliant symbols. A FNC1 character is used in the first position of data encoded. It enables scanners to process the information according to the GS1 system rules.

Example: A GS1 DataMatrix symbol encodes the data element AI (01) with the GTIN 10012345678902 and generates the transmitted data string]d201100123456789 02.

The data transfer follows the same basic rules that apply to the concatenation of data elements of GS1-128 symbols. Data elements of no pre-defined length are separated with the ASCII character 29 (GS character) from the next data element.

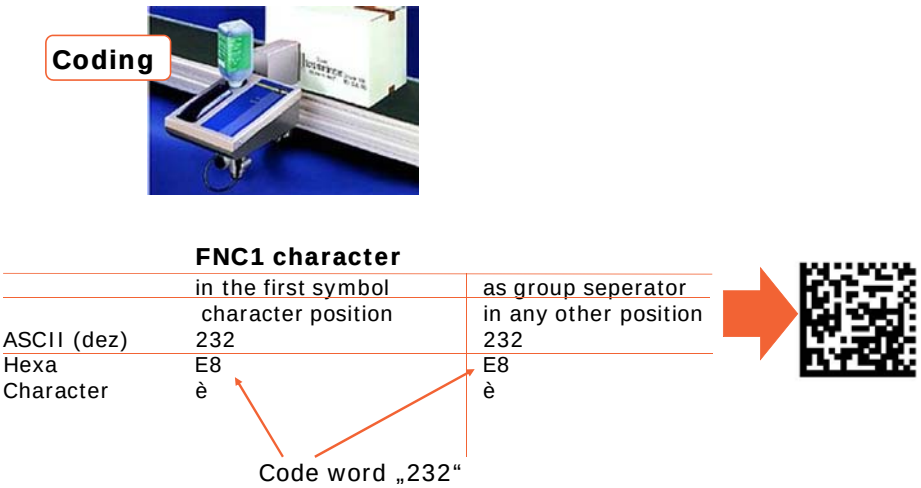


Fig. 9: Coding of the FNC1 character

The coding of the FNC 1 character means using the code word value "232" for both, the start character and the group separator. The decoding characters are different: the symbology identifier "]d2" at the beginning and the ASCII character “GS” for group separator.

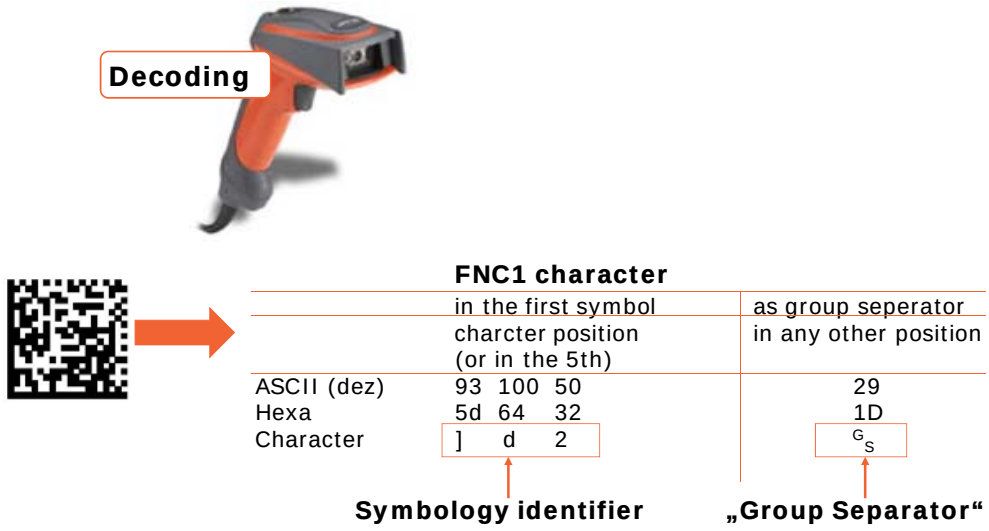


Fig. 10: Decoding of FNC1 character

5 Printing techniques

The following section provides an overview of the key printing techniques of GS1 DataMatrix. It is focused on their strengths and weaknesses. It provides an overview that enables the user to formulate its printing requirements more easily.

5.1 Basic software features

To generate a GS1 DataMatrix code, software is needed that provides the data for the printing system according to the above defined specifications (and in accordance with ISO / IEC 16022 standard). In practice an error-prone area is the programming of the FNC1 character as a start character and a group separator. Nearly every software vendor has its own method to ensure the correct implementation in the code word value "232". It is advisable to check carefully whether the software has this feature. Other special characters such as the ASCII character 29 for "GS" should be coded correctly.

Lots of good software programs provide a "wizard" that helps users in testing and encoding data in accordance with GS1 rules (e.g. selection of application identifiers, data format, check digits, etc.). Software can be either in the integrated printing system or be independent of it.

- Software independent from the printing system

This software can work with any kind of printer. The underlying system generates information to be printed and transmits it as either a print file or as an image file to the printing system.

- Software integrated in the printing system

This type of software is equivalent to a direct, internal logic. The printing system itself generates the GS1 DataMatrix code. This is particularly helpful if the encoded data and / or the size and shape of the symbol vary from one product to another. The necessary processing time can be shortened considerably when software is used, which is integrated directly into the printing system. This is for example, if a unique serial number has to be generated for each package and must be coded on each package.

5.2 Varieties of printing techniques

In the following there are only "on-demand" printing techniques described, because they are especially suited to encode dynamic information such as batch or serial number. Conventional methods such as flexographic or offset printing, deliver excellent results when coding static information, such as the GTIN in an EAN-13 bar code. These are neglected at this point.

The printing processes which are suitable for producing a GS1 DataMatrix code with secondary information are the following ones:

- Thermal transfer printing
- Inkjet or inkjet printing
- Laser marking
- Directly by dot peen marking

The right choice depends largely on the surface properties and the process requirements.

- Thermal transfer printing

The thermal transfer printing is probably the most widely used technology for printing on-demand bar code labels. The printhead consists of heatable dots, which are controlled individually by a microprocessor, i.e. individually heated and cooled. Heated dots cause the thermal transfer printer that a single color-band delivers color (wax or resin) and adheres to the paper or plastic film. Qualitatively good results can be achieved if the label material and the ink ribbon are well coordinated. The choice of a ribbon is therefore normally influenced by the surface treatment integrity (or its ability to absorb ink and its smoothness), the heat of the

print heads, and the required printing speed. The quality of the printed symbol should be checked regularly, because one of the main problems of the thermal transfer prints is the failure of printhead elements which can cause unwanted gaps.

- inkjet printing

The inkjet method requires no contact between the printer and the surface. The ink droplets are controlled by a microprocessor and sprayed contactlessly from a tank through nozzles onto a surface to form a dot matrix code. There are two different types of inkjet printers:

- Continuous inkjet printers and

- Drop on Demand inkjet printers and piezo inkjet printers

The print heads have to be positioned anywhere close to the surface in both processes. In generell, the inkjet technique is suitable for a wide range of materials and surfaces. Matrix codes produced by inkjet printers often have irregular edges. This is partly due to the porosity of the material to be printed on. Another reason is the not quite identical shape of the individual ink splashes. Symbols can be produced with good quality when printed on a suitable substrate and when a high resolution and fast-drying ink is chosen. Special attention must be paid to the constant speed and precision with which the object passes by the printhead.

- Laser marking

Laser etching or laser engraving techniques use precisely controlled lasers to engrave the matrix code on the product. The high concentration of the laser burns or etches the symbol. Therefore, it is necessary to have a computer in conjunction with a series of mirrors and lenses for focusing the laser. Basically, the type and power of a laser light source has to be finetuned with the item to be marked. The spectrum of the printing options and results is large.

- Dot peen marking

This method is particularly suitable for direct labeling of solid materials such as metal, plastic, wood, etc. It can be used for the application of any information on the item (text, date, logo, GS1 Data Matrix code, etc.). Controlled by a microprocessor and fixed on the die head, the needles are pushed strongly on the surface of the item in order to achieve a notch effect.

5.3 Selection of a printing technique

In selecting the appropriate printing method various parameters must be checked, such as

- the material

The table below shows a basic compatibility of different materials with the printing techniques described. In any case, it is recommended to ensure through testing in advance that a particular printing technique is suitable for the specific application environment. These tests should cover all aspects of technology, such as ink, paint, surface condition, maintenance cycles, etc.

	Paper	Corrugated paper	Glas	Plastic	Metal
Inkjet	Yes	Yes	Yes	Yes	Yes
Laser etch	For specific colors or specific painting	For specific colors or specific painting	Under specific circumstances	If contrast is achieved or specific painting exists	Paint or oxidate
Thermotransfer (on demand)	Suited for self-adhesive labels	No	No	Plastic foil	No
YAG Laser	Colored background or specific painting	Colored background or specific painting	No	Yes	Yes
Inkjet (on demand)	Yes	Yes	No	No	No
Direct marking (DPM)	Film transfer	Film transfer	No	Yes	Yes

- the space available

The actual required size of the symbol with all relevant information and plain text must be into line with the available size and printing technology. In general, better printing and scanning results can be achieved with symbols having a higher magnification factor than codes having a lower X-module. However, many factors influence the available square, including the legally required safety information.

- the printing speed

If symbols are printed online (e.g., as part of the production line of an article), then the speed of the conveyor belt of the production line plays a major role in the selection of an appropriate printing method.

- Industry or sector-specific regulations and laws (like e.g. in the healthcare and automotive sector)

In many markets, industries and countries exist requirements for the content and the quality of GS1 DataMatrix codes. These should be considered when selecting the appropriate printing technology.

- Customer requirements

As with all business transactions the customer needs must be pulled into the equation. A demand from customers could be a very high quality requirement, which could be fulfilled only through a particular printing process. Within the cooperative basic idea of the GS1, all partners of the supply chain should work on the basis of reasonable needs and cost-benefits relations.

5.4 Print quality

The quality of the symbol is of great importance and should definitely be included in the routine of quality control of the production process. The following requirements should be coordinated with the technology provider:

- Fully compliant with ISO / IEC 16022 standard.
- The software supports the GS1 application identifiers.
- It is the Data Matrix ECC 200 version (and not older).
- The FNC1 character is supported as a start character and as a group seperator.

Of particular importance is also the targeted X-dimension size, because the actual printable size of the module depends on the size of the print head.

5.5 Color and contrast

Contrast is the technical term for the difference between dark and light areas in a bar code. It is measured how this difference can be detected by the scanner. The contrast is strongly influenced by the color and reflectance of the substrate. The following simple rules will help to achieve an appropriate color combination and thus a good symbol contrast:

- Black print on a white background is the best color combination.

- Dark areas should be printed with a dark color (black, blue or another color that has a high proportion of black).

- Bright areas should be highlighted with a bright and reflective color (white, yellow or red, what appears as white for a scanner).

- Intermediate colors that are neither light nor dark, should not be used.

- Some substrates, especially highly reflective metal, and highly reflective ink (e.g. gold, silver) should be avoided as these can "dazzle" the scanner.

Contrast problems are frequently caused by

- a bad choice of color for dark and / or bright areas
- the use of a transparent background,
- the "blurring" of the dark color in the bright areas
- strong reflection of very strong bright or shiny surfaces.

6 Advantages

The advantages of using the NTIN can be summarized as follows:

- The PZN as a German solution is integrated into a global standard concept.
- The solution is future-compatible, i.e. adaptation investments are sustained
- The use of globally accepted GS1 technologies such as GS1 DataMatrix is ensured.
- The NTIN provides security in the face of emerging changes in market structures.
- With the use of the NTIN, users are involved in the communication structures of the worldwide GS1 network.

7 Implementation of GS1 standards in Europe

A glance at Europe shows that the harmonization of identification and coding solutions for medicines in Europe advances.

7.1 Use of GTIN

In Europe, 17 countries already use a GTIN to identify a drug in an EAN-13 compatible structure. These include, for example, Ireland and the UK.

Turkey has also opted for the use of the GTIN. Since 2009 the Turkish authorities require the GS1 Data Matrix for the labeling of medicines. Here, secondary information like batch number, expiry date and serial number is encoded in addition to the GTIN on the drug packages.

7.2 Use of NTIN

In three European countries a NTIN structure in an EAN-13 compatible format is used. These are inter alia Austria, Greece and Spain.

In France, since 1 January 2011, the new provisions of the standard for the labeling of medicines made by the French Medicines Agency AFSSAPS (Agence française de sécurité sanitaire des produits de santé) are in force. They ensure the traceability of pharmaceutical products from production through to the patient and increase patient safety. So far, the French 7-digit CIP code was printed in a linear bar code. Since early 2009, drugs are identified with a NTIN, i.e. the CIP code in a 13-digit GS1 format and encoded in the EAN-13 bar code. End of 2010, the conversion to the 2D code GS1 DataMatrix was completed The GS1 DataMatrix offers additional capabilities, thus the coding of the batch number and the expiry date in addition to the NTIN is required.

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