

Use of GS1 2D Matrix Data Carriers in Healthcare

Purpose

The purpose of this paper is to provide guidance on the use of 2D Matrix barcode symbols in the healthcare industry. This is done through discussion of the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers, their use in the healthcare supply chain, and the **Global GS1 Healthcare preference for the use of GS1 DataMatrix** for GS1 Keys typically found on trade items (i.e. GTIN, GRAI, GIAI and SSCC when applicable).

Executive Summary

The members of GS1 Healthcare continue to support the use of GS1 DataMatrix as the only endorsed 2D Matrix data carrier for encoding GS1 Keys on healthcare trade items and logistics labels. For use cases or processes that require a single data carrier selection for all keys, to maintain consistency and to minimise training and additional expenditure, the recommendation is the use of GS1 DataMatrix for all GS1 Keys within those implementations.



GS1 is finalising the Digital Link standard to enable mobile devices (i.e., smartphones) to scan the single barcode (i.e., linear or 2D) and access digital content about the product.

This eliminates the need to add a QR barcode to the product or pack in Healthcare. The GS1 Digital Link standard helps reinforce the GS1 Healthcare One-barcode initiative. Meaning, manufacturers, distributors, hospitals and pharmacies will still use the ubiquitous barcode for years to come, for many different purposes like traceability and point-of-care scanning.

Yet, now with GS1 Digital Link, they have the opportunity of using a single barcode to access digital information about the product. Refer to the <u>GS1 Digital Link Standard</u> for more information.

Regulatory requirements – GS1 DataMatrix as a preferred option

The unique identification of healthcare products for track and trace purposes - from the point of manufacture to the point of administration - is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 DataMatrix as that data carrier.

For example, GS1 DataMatrix was widely used to uniquelyidentify secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and for primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, Egypt, Ethiopia, India, Jordan, Korea, Saudi Arabia, Turkey and the U.S., as well as being required as part of the European Commission's regulation for medicines verification in Europe. It is also recommended for use on vaccines in Canada and is the recommendation on vaccines by WHO and requested by GAVI and UNICEF as well as other drug products in the area of Humanitarian Logistics.

Healthcare industry practices – a drive for one barcode symbol on trade items

While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain from the point of manufacture to the point of administration, ISO/IEC QR Code is at this time primarily found on packages as a link to marketing information about a product. However, the inclusion of more than one barcode symbol on the same package or label is not recommended by GS1 Healthcare and its global community. Both objectives, traceability as well as access to product information can be accomplished with a single data carrier.

Multiple barcode symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the wholesaler/distributor/caregiver/pharmacist might find it difficult to identify which barcode should be or has been scanned/read. The GS1 Healthcare Provider Advisory Council (HPAC) developed a <u>position paper</u> highlighting issues with barcode symbols, which are hindering the implementation process in hospitals.

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the barcode and variable information dynamically as well as in multiple places on an item, two or more printing and verification systems may need to be installed and maintained. This leads to more training & processes, more equipment, and more risk of errors that could be avoided.

Although the application of dynamic information in barcode symbols is relatively new to healthcare applications, ISO/IEC Data Matrix was developed and in use in global industrial applications before ISO/IEC QR Code. GS1 DataMatrix, which is derived from ISO/IEC Data Matrix, already has an install base with background knowledge for application and use in these types of product and packaging applications. GS1 DataMatrix is widely used in the healthcare sector, based upon the "industrial" practices in other sectors.

However, most consumers are not fully informed on the benefits GS1 DataMatrix and often may not be able to distinguish it from ISO/IEC QR Code. The creation and scanning of GS1 DataMatrix has been improved and optimised to better meet the needs of the supply chain and consumers can easily scan it with smartphone applications.

Considering this, it is important to acknowledge all the work accomplished over the past years by the industry to maintain ISO/IEC Data Matrix and improve its printing quality, given that all these efforts can also be applied to the Business-to-Consumer (B2C) needs.

Data Matrix and QR Code - similar technical capabilities

In comparing the data carriers; ISO/IEC Data Matrix (known in the GS1 System as GS1 DataMatrix) and ISO/IEC QR code (known in the GS1 System as GS1 QR Code) from a technical and practical implementation point of view (e.g., amount of data to be encoded, high-level technical capabilities of 2D Matrix barcodes, error prevention and detection, etc.), there is no significant practical advantage to use one versus the other. Both data carriers are 2D Matrix barcode symbologies that can encode large amounts of data in small areas and employ " error correction". Potentially, the only unique benefit in the use of QR code over Data Matrix is a higher efficiency when encoding (Japanese) Kanji characters. However, this does not serve as a competitive advantage in the GS1 System, because only digits (numbers), the Roman alphabet and a set of selected characters are allowed to be encoded in GS1 standard symbologies. Refer to GS1 General Specifications section titled "The GS1 subset of international standard ISO/IEC 646, table titled GS1 AI encodable character set 82", for more information.



Release 2.0, October 2019 Over the last few years, there has been a significant growth of free and downloadable applications (referred to as Apps') for smartphones and mobile communication devices that allow the consumer to remotely access information about a particular item or product. Both GS1 DataMatrix and GS1 QR Code can facilitate connectivity to product information with these types of Apps. Previously, B2C apps were were generally limited to UPC/EAN, ISO/IEC QR or other proprietary symbols. Nowadays, Apps have been developed which can scan DataMatrix as well, giving greater user flexibility.

Through GS1's increased efforts, Apps are able to access product information via the GS1 Global Trade Item Number (GTIN), encoded dynamic product data, access to a trusted URL all via the 2D barcode data carriers (i.e., GS1 DataMatrix, GS1 QR Code). This is partially enabled by additional information in the GS1 Application Identifiers (AIs) associated with the GTIN and encoded in the data carrier. For example, when scanning a GS1 DataMatrix on pharmaceutical packaging, the user will be able to identify the GTIN of the trade item and any relevant encoded AIs; such as expiration date, lot/batch number and/or serial number. It potentially could then provide access to the product's Electronic Information for Use, patient leaflet, or even to an instructional online video. Refer to the <u>GS1 Digial Link</u> for more information.

2D Matrix Data Carrier Selection – GS1 Global Healthcare Conclusions

Considering all the aspects of this discussion, GS1 Healthcare and its global members continue to strongly support the implementation and use of GS1 DataMatrix as the only endorsed 2D Matrix data carrier for encoding GS1 Keys typically found on trade items in healthcare (i.e. GTIN, GRAI, GIAI and SSCC when applicable). In this regard, GS1 DataMatrix is the only permitted GS1 2D Matrix barcode data carrier for use with GS1 Keys when associated with healthcare products (i.e. regulated healthcare trade items).

When considering GS1's 2D Matrix data carriers for encoding other GS1 Keys typically used in the healthcare sector (i.e. GLN, GDTI and GSRN), GS1 Healthcare and its Global Members see no overwhelming reason to mandate only the use of GS1 DataMatrix and consider GS1 QR Code an equal choice to be considered by users. For those individual healthcare users or groups of healthcare users whose specific applications or processes may require a single data carrier selection for all GS1 Keys within their use-case, the primary recommendation would be the use of GS1 DataMatrix for all keys to maintain consistency with existing healthcare product use as well as minimising the need for additional or "cross" training, duplication of processes, further expenditures, etc.

To help bring awareness of the positive effects of the use of GS1 DataMatrix as the single 2D Matrix data carrier for healthcare trade items, GS1 Global Healthcare encourages any new investments and education in the areas of printing and scanning to encompass use of GS1 DataMatrix as applicable.

About GS1

GS1 is a neutral, not-for-profit organisation that develops and maintains the most widely used global standards for efficient business communication.

We are best known for the barcode, named by the BBC as one of "the 50 things that made the world economy". GS1 standards improve the efficiency, safety and visibility of supply chains across physical and digital channels in 25 sectors. Our scale and reach – local Member Organisations in 114 countries, 1.5 million user companies and 6 billion transactions every day – help ensure that GS1 standards create a common language that supports systems and processes across the globe. Find out more at www.gs1.org

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. The evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare members include more than 100 leading healthcare organisations worldwide.

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