Standard Guideline for Two dimensional (2D) Symbol Marking on Steel Instruments

June 1, 2017
Japan Association of Medical Devices Industries（JAMDI）

1. Purpose

The marking of two dimensional (2D) symbol on steel instruments is becoming increasingly essential to ensuring patient safety and traceability at the occurrence of an incident. Especially, the unique ID indicated on the body of instruments is highly useful in order for medical institutions as well as the Marketing Authorization Holders (MAHs) to identify and/or recall defective lots, to control the sterilization of steel instruments used for vCJD patients, and to manage rented instruments.

This guideline has been established as standard specifications for data structure and data carrier, etc. in marking a 2D symbol on the body of steel instruments provided by MAHs in order to facilitate safety control by medical institutions and to prevent problems for traceability.

We ask domestic and foreign manufacturers of steel instruments and MAHs (in Japan) for their understanding and cooperation with the implementation of the guideline.

2. Definition of steel Instruments

“Steel Instruments” covered by the guideline are instruments made of stainless steel, aluminum, copper alloy, titanium, ceramics, etc. to be reused in operations and treatments after recycling process (ex. washing, sterilization) has been performed.

The instruments used in operations and treatments which do not fall under the category of medical devices stipulated in the Pharmaceuticals and Medical Devices Law may also be handled in accordance with the guideline.

3. Principle of the Code System

The guideline adoptsGS1 Standards specified in “UDI Implementation Guide for Medical Devices” jointly formulated and issued by the Japan Federation of Medical Devices Association (JFDA), the GS1 Japan, and the Medical Information System Development Center(MEDIS-DC) in March 2016.

(1) Data structure

The code should consist of a GTIN (Global Trade Item Number) and a serial number, and include the following information in the following order.

Data structure should be 26 ~ 38-digit (26-digit is recommended)

① Application Identifier (AI) of GTIN : 01 (2-digit, fixed)

② Leading zero : 0 (1-digit, fixed)

③ GS1 Company Prefix : A unique string to identify companies issued by GS1Japan*Note 1

④ Item reference: tem identification number assigned by each company* Note 1.

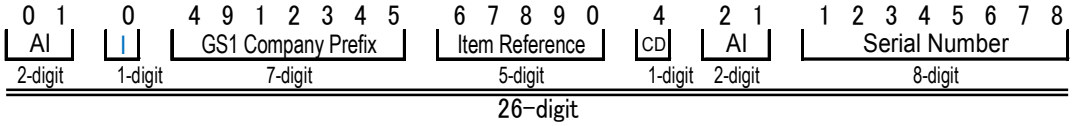
⑤ Check digit : A final digit calculated from the value of ③ and ④

⑥ Application Identifier (AI) of serial number : 21 (2-digit, fixed)

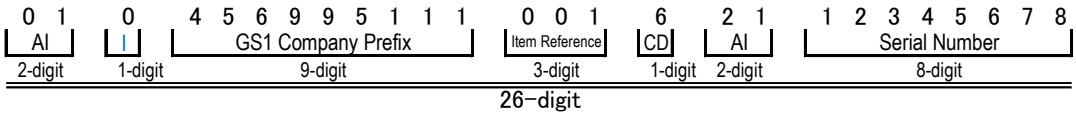
⑦ Serial number allocated by each company : 8-digit is recommended *Note 2.

Note 1: Standard composition of the data field

A. In case of 7-digit GS1 Company Prefix



B. In case of 9-digit GS1 Company Prefix

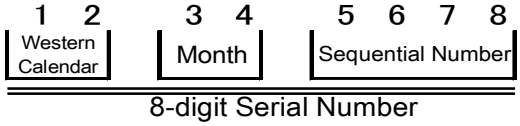


Note 2: Recommended specifications of serial number

The following 8-digit indication is recommended for serial number.

A company might control the serial number with the different code structure from the recommendation, as GS1 defines the serial number as one to 20 digit numeric or alphanumeric code.

However considering efficacy, it is not preferable to use many digits as it may affect the readability.



(2) (Data Carrier – choice of symbol, marking location and size

Among ISO standard two dimensional (2D) symbols, GS1 DataMatrix is recommended for the data carrier, which is defined by GS1 Specifications. In encoding data in GS1 DataMatrix, “FNC1” has to be set at the head of the data elements as below.

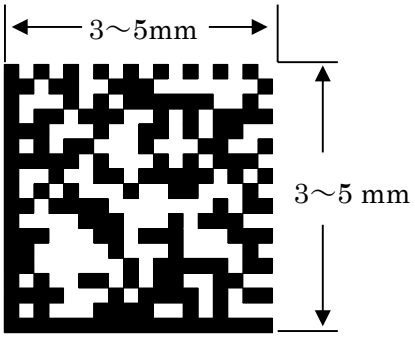
Data Elements FNC1 01 04912345678904 21 17075678

(AI) GTIN (AI) Serial No.

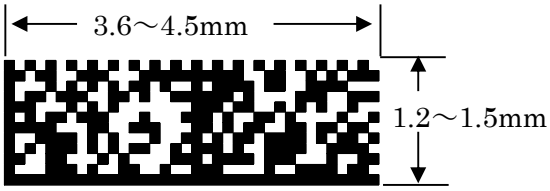
In the future, utilization of RFID tag, etc. will be examined based on the technical trend and reading accuracy requirement.

In principle, GS1 DataMatrix should be marked on two different locations of an instrument. The appropriate size of GS1 DataMatrix is 3 to 5mm square in consideration of marking accuracy and reading capability. The format of GS1 DataMatrix should be chosen depending on the size and shape of steel instruments as shown below.

① In case that 3mm square or larger space can be secured for marking



② In case of steel instruments in bar shape on which 3mm square space cannot be secured for marking



(3) Registration of product codes in the database

In accordance with the guideline, in principle, the product code (GTIN-13) encoded in the two dimensional (2D) symbol is to be registered in the MEDIS-DC database for medical devices.

(4) Miscellaneous

This guideline has been established as the standard specifications for the Association whose members market steel instruments, and the marking described in the guideline is not the legal requirement by the Pharmaceutical and Medical Devices Law. When marking two dimensional (2D) symbol on steel instruments owned by medical institutions, medical device loaners, etc., it is preferable to mark the symbol in accordance with the guideline in order to avoid confusion with the symbols on instruments newly provided by MAHs.

In addition, the guideline does not refer to marking devices, two dimensional (2D) symbol readers, and recycling process management system.