Operation Guide for Direct Marking on Medical Devices

Ver. 2.6
Sep. 2024

GS1 Healthcare Japan

Introduction

In medical treatment, marking of product identification codes on medical devices and traceability (history tracking) are being seen as having worldwide importance due to the necessity of reassessment of treatment process, risk management, etc.

The International Medical Device Regulators Forum (IMDRF), in which regulatory authorities in Japan and other countries participate, issued a Unique Device Identification (UDI) guidance in December 2013 to identify and manage medical devices and ensure traceability. In the United States, barcode labeling and registration in the medical device database (GUDID) have been made incrementally mandatory since September 2014 in accordance with FDA UDI regulations, and the Medical Device Regulations (MDRs) including UDI regulations were also published in the EU in May 2017. In addition, many countries and regions besides the EU and US are also starting UDI regulations. In Japan, barcode labeling for medical devices has been promoted through notification by the MHLW(Ministry of Health, Labour and Welfare) since 2008, but in November 2019, the revision of the Pharmaceutical and Medical Device Act was passed, and the labeling of barcodes became mandatory under law. In both medical industries and hospitals, the utilization of ICT(Information and Communication Technology) for the traceability of pharmaceuticals and medical devices is being promoted. Concretely, it is expected that international standardized barcodes would be displayed on every pharmaceutical and medical device in unit of use for patients, and that the information derived from scanning the barcodes is utilized for patient safety and also used as big data for the evaluation of safety and effectiveness with real clinic data.

Among various medical devices, those such as surgical steel instruments that are reused multiple times through sterilization or disinfection between uses are considered to be essential Direct Marking (Direct printing). Direct Marking has become mandatory by 2022 in the US and will be mandatory by 2027 in the EU.

GS1 Healthcare Japan recognized the global flow of Direct Marking, and in March 2011 issued the "Steel Instrument Marking Operation Guide", which mainly summarizes the handling of UDI in foreign countries and Japan until then. Direct Marking and the traceability system using it were initially operated only in some advanced medical institutions, but it can be said that the continued technological development thereafter has greatly improved the performance of Direct Marking and scanning readers, finally allowing them to enter the stage where they can be used in many medical institutions.

Therefore, the "Operation Guide for Direct Marking on Medical Devices" was issued in 2017 and newly incorporated the latest information, in place of the "Steel Instrument Marking Operation Guide". It will greatly contribute to patient safety, when administration and control of medical devices are carried out under common understanding among healthcare providers and the industry. We hope that this document will be useful for the operation of traceability in future medical care.

<div align="right">

September 2023
Seizoh Nakata
Chief Director for International Standards and Regulations
GS1 Healthcare Japan
(Administrator of Itami City Hospital)

</div>

Positioning of this manual

- This document presents the latest information on Direct Marking and scanning technologies for two-dimensional barcodes (GS1 DataMatrix) for medical devices, and examples of their utilization in medical institutions.
- Direct Marking regulations are being established in countries and regions around the world. However, the targets and contents may differ, so when marking, we would like you to check the regulatory status of the country or region.

*) GS1

GS1 is a global, neutral, non-profit standards organization made up of more than 110 national and regional representatives that promotes informational standardization for more efficient and transparent supply chains. The code structures and barcodes standardized by GS1 are called GS1 standards and are used as international standards in the global supply chain.

**) Direct Marking

It is also called direct part marking, but it is referred to as Direct Marking in this manual.

1	**What is Direct Marking?**

Direct Marking is a generic term for technology that marks barcodes or symbols directly on products in various ways, rather than affixing labels to products (products, parts or their packaging), and technology that automatically recognizes marked barcodes or symbols.

Direct Marking is used,
  ① When the product is small and the space for affixing the display label cannot be secured
  ② When durability against cleaning and sterilization is required because products are used repeatedly

Since most steel instruments and endoscopes are small and precise and are repeatedly used through disinfection and sterilization processes, sticking space and long-term durability become a problem for ordinary display labels such as paper and film. There is also the risk of a medical incident that should never happen, such as peeling off of the display label during an operation or it remaining as a foreign substance in the patient's body.

For this reason, UDI regulations in the EU, the US and other countries require Direct Marking as a means of realizing permanent labeling on repeatedly used equipment. In Japan, although not subject to regulatory mandates, the implementation of Direct Marking is recommended within the medical device industry in consideration of international consistency and traceability management in the medical field.
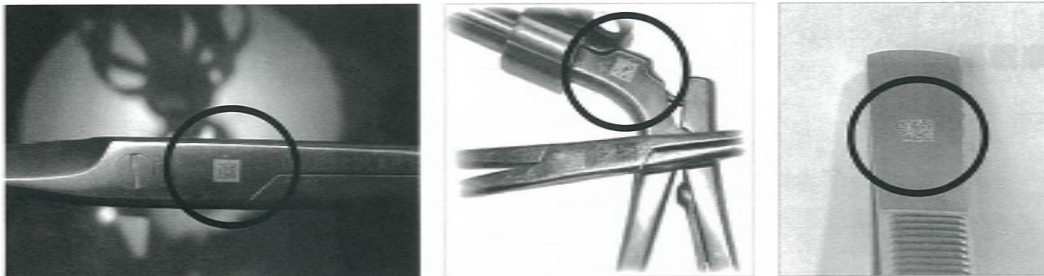

Fig. 1.1 Examples of Direct Marking on various medical devices

Table 1-1 Direct Marking Compliance Date for Medical Devices According to UDI Regulations in the EU and the US.

US

Class	Compliance Date
Life-Supporting, and Life-Sustaining Medical Devices	September 24, 2015
ClassⅢ	September 24, 2016
ClassⅡ	September 24, 2018
Class I	September 24, 2022

EU

Class	Compliance Date
ClassⅢ and Implantable Medical Divices	May 26, 2023
ClassⅡa and ClassⅡb	May 26, 2025
Class I	May 26, 2027

<table>
<tr><td>**2**</td><td>**GS1 standards**</td></tr>
</table>

Code structures and barcodes of GS1 standards are used for identifying medical devices not only in Japan but also in many countries. The codes, barcode symbol, human readable interpretation (HRI) and symbol sizes are as follows. See GS1 General Specification for details.
https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

1) Code structure

A code structure of GS1 standards consists of a GS1 identification key, which is fixed information for identifying products or assets, and attribute information, such as a serial number and an expiration date, which varies with each manufacturing of the products, each of which is separated by a 2- to 4-digit number called GS1 Application Identifier (AI).

The GS1 identification key used for Direct Marking of the medical device is GTIN or GIAI, and the serial number is mainly used as the attribute information.

(1) GTIN for Direct Marking by manufacturers

GTIN (Global Trade Item Number) is used to identify products. GTIN is a generic term for international product identification codes standardized by GS1 and is an 8-, 12-, 13-, or 14-digit code consisting of a GS1 Company Prefix, an Item reference, and a Check digit (GTIN-14 includes an Indicator as a component). When distinguishing each one clearly, it is called GTIN-8, GTIN-12, GTIN-13, GTIN-14 according to the number of digits of the code.

The AI representing GTIN is 01. The GTIN format while using the AI is always 14 digits, so when GTIN is less than 14 digits, the prefilled "0" (leading 0) is required to fill the empty space.

Note that when the code is represented as Human Readable Interpretation (HRI), the AI is enclosed in parentheses ( ). (Note that parentheses are not encoded as barcode data.)

Example:
GTIN: 4569951110016
Serial number: 42345A-2
(01) 04569951110016(21)42345A-2

(01)04569951110016
(21)42345A-2

(*) JAN (Japanese Article Number) code, which is known as a commodity identification code in Japan, is a Japanese local name and is the same as GTIN-13. Similarly, U.P.C. (Universal Product Code) utilized in North America is the same as GTIN-12.

(2) GIAI for Direct Marking by medical institutions

GTIN is used when manufacturers set identification numbers for medical devices, but when the product does not have GTIN and medical institutions want to administrate them as assets, GIAI (Global Individual Asset Identifier) can be assigned by the institution using the institution's GS1 Company Prefix. GIAI is a code up to 30 digits composed of a GS1 Company Prefix and an Individual asset reference. The AI representing GIAI is 8004. GIAI shall only be used to manage assets but not for trade items.

Example:
GS1 Company Prefix: 456995111
Individual asset reference: 100025A
(8004) 456995111100025A

(8004)456995111100025A

2) Barcode symbol

GS1 DataMatrix is used for Direct Marking of medical devices. GS1 DataMatrix is based on the Data Matrix specified in ISO/IEC 16022/JIS X 0512 so that GS1 Application Identifiers can be used.

There are square and rectangular shapes, but squares are usually used preferentially in comparison with rectangles, because the specified maximum symbol size is large.

(01)04569951110016
(21)42345A-2

(01)04569951110016
(21)42345A-2

3) Human Readable Interpretation

Human Readable Interpretation (HRI) shows the data encoded in a barcode and is primarily displayed below the barcode, but can be omitted in the case of Direct Marking.

4) Barcode size

The following table shows the dimensions of Direct Marking on healthcare products such as medical devices defined by GS1 standards.

Direct Marking Specifications for GS1 DataMatrix for Medical Products.

Print Instruction [*1]	Module Width (X) mm (inch)			Quiet zone
	Minimum	Target	Maximum	
Ink-Based Direct Marking	0.254 (0.0100")	0.300 (0.0118")	0.615 (0.0242")	1X, On all four sides
Non-Ink-Based A: - Laser marking	0.100 (0.0039")	0.200 (0.0079")	0.300 (0.0118")	1X, On all four sides
Non-Ink-Based B: - Dot peen marking	0.200 (0.0079")	0.300 (0.0118")	0.495 (0.0195")	1X, On all four sides

NOTE) Extract from GS1 system symbol specification table 7 of GS1 Comprehensive Specifications

*1: There are two basic types of non-ink-based direct part marks: those with "connected modules" in the "L"-shaped finder pattern (Non-Ink-Based A) created by Direct Marking technologies such as laser or chemical etching and those with "non-connected modules" in the "L"-shaped finder pattern (Non-Ink-Based B) created by Direct Marking technologies such as dot peen. Due to the marking technologies and characteristics of reading they each have varied ranges of X-dimensions and different quality criteria recommended and may require different reading equipment.

✓ See ISO/IEC 15415 (JIS X 0526) and ISO/IEC 29158 for qualities.

✓ In practical application, where very small symbol sizes are needed, it may be necessary to work with GS1 DataMatrix module X-dimensions smaller than those suggested. Where dimensional restrictions prohibit the application of a full-size code, reduced X-dimension AIDC marking is encouraged to facilitate information capture. It should be noted that these practices may limit the symbol effectiveness, including but not limited to:

- the effect of smaller X-dimensions on reading performance,

- the need for, and limited availability of, special scanners/imagers for reading,

- special processes for marking,

- the overall cost considerations.

These smaller X-dimensions should therefore only be used internally or by mutual agreement between trading partners.

In order to maintain high reading performance, it is better not to mix different marking methods in a single reading environment. Laser etching is recommended for marking small instruments.

3 Examples of use in medical institutions

1) NTT Medical Center Tokyo
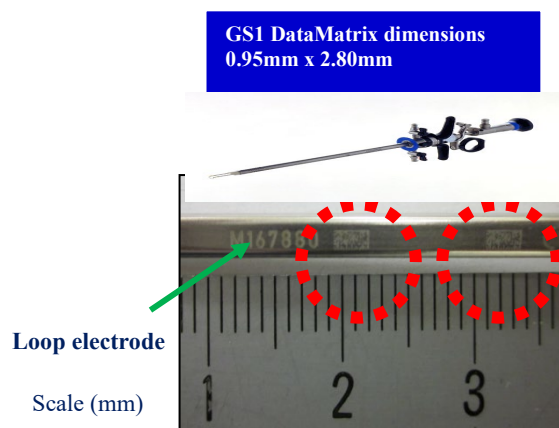### Endoscope Component Traceability Management System

(1) Outline of the facility

1951 Opened as Kanto Teishin Hospital
JCI (Joint Commission International) Certified hospitals
Number of beds: 597
Number of outpatients: 1,914/day
Number of operations: 5,016 operations/year (Fiscal 2016 data)

(2) History of introduction

NTT Medical Center Tokyo started Direct Marking of Data Matrixes by laser marking in 2007, and individual product control with serial numbers has been tackled since then. In 2011, advances in marking technology made it possible to imprint GS1 DataMatrix on microscopic parts such as the endoscope components. Accordingly, they decided to use GIAI (Global Individual Asset Identifier) as an identification key for endoscope components, and Direct Marking with GS1 DataMatrix encoded GIAI was started. It was the first use of GIAI in Japan.

GIAI consists of three components: hospital code (GS1 Company Prefix of NTT Medical Center Tokyo), medical department code (optional), and equipment serial number. Direct Markings have been conducted on two places, the front and back, of every endoscope component in terms of scanning operability, as is recommended for other steel instruments. By selectively using the laser marking and dot peens, it is possible to work with various materials such as titanium alloy, ceramics and plastic resin in addition to stainless steel.

GS1 DataMatrix dimensions 0.95mm x 2.80mm

Loop electrode

Scale (mm)

(3) Traceability Management System for Endoscope Components

The endoscope component traceability management system consists of two parts: historical management of used devices and control of set assembly, both of which are the core of the disinfection and sterilization process. Figure 3-1 shows the flow of the disinfection and sterilization process for endoscope components.
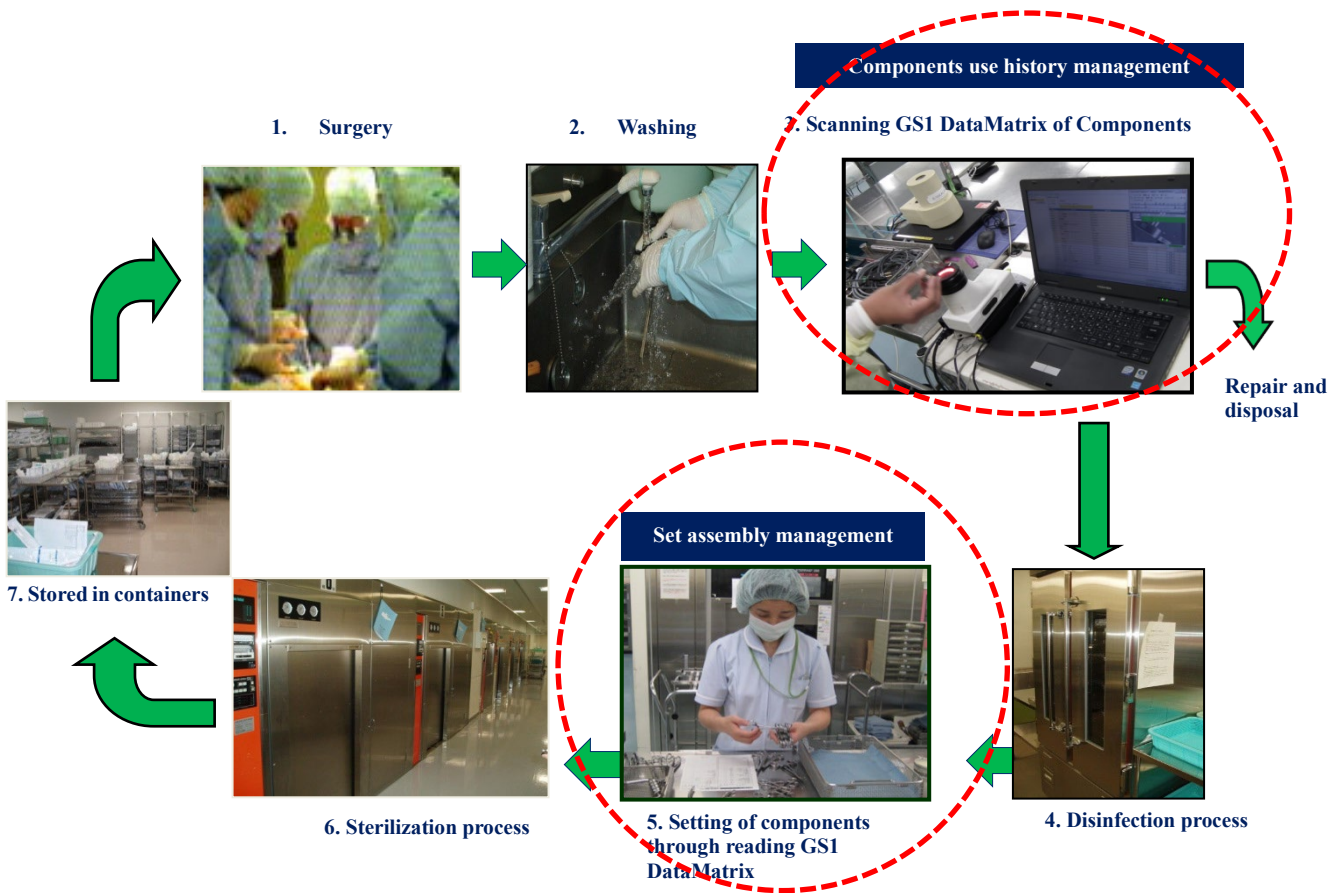
Fig. 3-1 Flow of disinfection and sterilization of endoscope components

① Use of endoscopes in an operation room. After operation, sort out the used components from unused ones.
② Simple washing of endoscope components is performed.
③ Read GS1 DataMatrix for used components. <Component use history management>
　　Components that have exceeded the preset number of times of use are displayed with a
　　warning on the system screen and can be disposed of or replaced individually.
④ Disinfection process is performed
⑤ Set components into sterilization containers after scanning GS1 DataMatrix on the components. <Set Assembly Management>
　　Components exceeding the preset sterilization frequencies set off a warning on the system screen.
⑥ Sterilization process is performed.
⑦ Store the sterilized containers.

(4) Effect of implementation

　　The implementation of the system incorporating Direct Marking has made it possible to trace which components of the sterile container were used for which operation, by using historical data. In addition to this, since the number of times of use and sterilization of endoscope components in sterile containers can be accurately grasped and controlled, the following effects can be obtained.

　　First, the data on the number of uses for each sterilization container enabled the identification of sterilization containers that were being used in every surgical procedure and those that were barely being used at all. This showed the need to reevaluate inventory and procurement plans for sterilization containers.

　　Second, data on the number of uses for each component enabled accurate assessments of the number of uses for all components, including the identification of components always being

used in surgical procedures and unused components (Figure 3-2).

For example, it was found that some conductors (loop-type electrodes), which were rarely used in operations, had always been set up in the sterilization container. Since the conductors had deteriorated and been worn out by repeated washing and sterilization, replacement is required when the preset number of times of sterilization is undertaken. It became possible to reduce the wasteful replacement of conductors by not setting up unused conductors in the sterilization containers.

In addition to the number of sterilization times, it became possible to grasp how many times the device was used until it was damaged. The timing of replacement and purchase of components in the sterilization container were visualized, and proper inventory control was greatly improved.
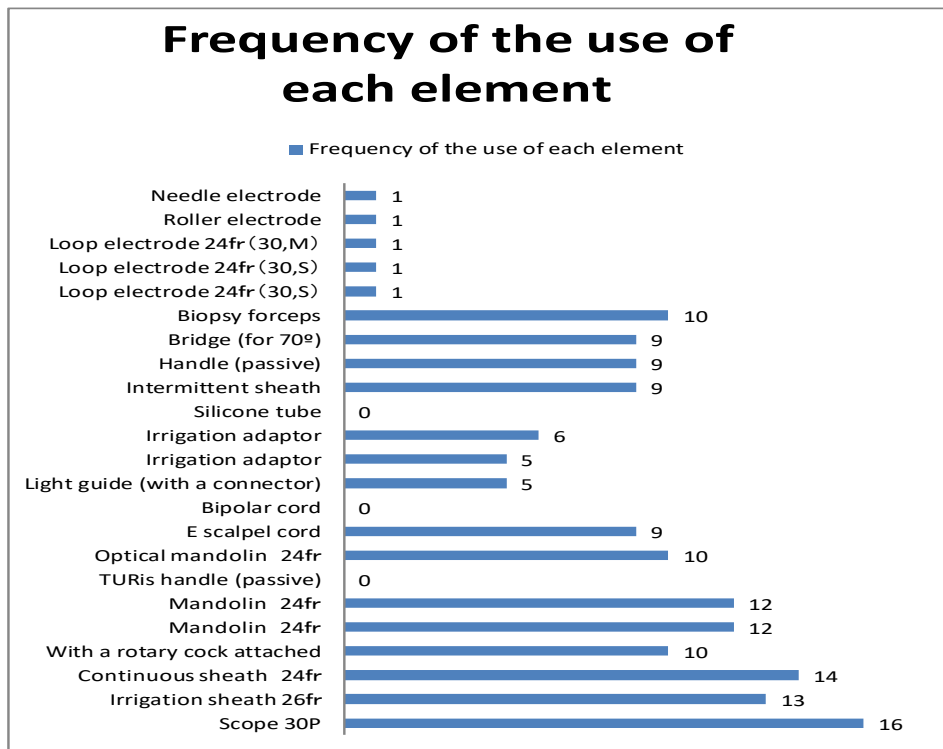

Frequency of the use of each element

■ Frequency of the use of each element

Component	Value
Needle electrode	1
Roller electrode	1
Loop electrode 24fr（30,M）	1
Loop electrode 24fr（30,S）	1
Loop electrode 24fr（30,S）	1
Biopsy forceps	10
Bridge (for 70º)	9
Handle (passive)	9
Intermittent sheath	9
Silicone tube	0
Irrigation adaptor	6
Irrigation adaptor	5
Light guide (with a connector)	5
Bipolar cord	0
E scalpel cord	9
Optical mandolin 24fr	10
TURis handle (passive)	0
Mandolin 24fr	12
Mandolin 24fr	12
With a rotary cock attached	10
Continuous sheath 24fr	14
Irrigation sheath 26fr	13
Scope 30P	16

Fig. 3-2 Frequency of use for each component

References:
・Chikayuki Ochiai; Implementation of standardized traceability system in Japan, GS1 Healthcare Conference 2016 Beijing China
・Hiroko Kozuka; New Challenge of Hospital Asset Management by GS1 Standards, Distribution and Systems, 154, 32-35, 2013

2) Fukui University Hospital: Integrated Sterilization Management System

(1) Outline of the facility
Special function hospital opened in 1983
Number of sick beds: 600
Number of outdoor patients: 1,418 people/day
Total number of operations: 5,920 operations/year (FY2018 data)

(2) History of introduction
According to the hospital rebuilding plan started in 2010, the "total sterilization management system" was introduced with relocation of wards and the Surgical Center and Central Sterilization Department in September 2014. The integrated sterilization system has been developed with the aim of improving the quality of medical safety and infection control by ensuring traceability of individual steel instruments, and improving work efficiency by concentrating a series of operation- and sterilization-related work at handy terminals. The system has been in full operation since September 2015. It is connected to the existing hospital network (including the electronic health record), and it operates in linkage with the information of operation schedule and operation equipment.

For identification of steel instruments, a GIAI-encoded GS1 company prefix of the hospital is used, and GS1 DataMatrix is imprinted by the laser marking equipment installed in the hospital. The size of GS1 DataMatrix is 2.5 × 2.5 mm square as a standard. Also, a 1.3 × 5.0 mm rectangular symbol is used depending on the shape of the instruments. In principle, two parts of each instrument are marked. If GTIN and the serial number are source-marked on the steel instrument, use them as they are.
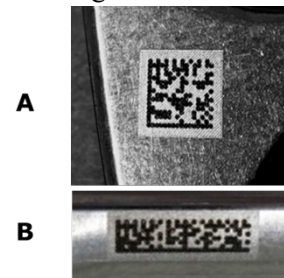
Fig. 3-3 GS1 DataMatrix directly marked on steel instruments
A: 2.5 mm x 2.5 mm
B: 1.3 mm x 5.0 mm

(3) The integrated sterilization management system
The workflow of the integrated sterilization management system is shown in Figure 3-4. By using portable digital devices, the system allows Fukui Hospital to manage information during each step of a surgical operation: collecting, cleaning, sterilizing and storing the surgical instruments along with preparing for operations. GS1 DataMatrix that is directly marked on each steel instrument is read twice—during the collection step after a surgical operation and during assembly. Detailed steps for reading the GS1 DataMatrix barcode and preparing for surgical operations are as follows:

① **Reading Direct Marking (GS1 DataMatrix) and Set Task**
Immediately after the completion of a surgical operation, scan GS1 DataMatrix on the steel instruments used during the operation, and finish counting all of them, checking if the prepared instruments have been collected. After cleaning the instruments, skilled staff members conduct a visual check, read the GSI DataMatrix again and assemble a surgery set, ensuring that all necessary instruments are ready.

Each surgery set has a GS1 barcode encoding GTIN, and scanning of the barcodes is carried out by smartphone-type portable devices at each step, except the collection and assembly described above.

② **Surgical Preparation Work Using Vertical Rotating Cabinet**
GS1 barcodes are used for checking at each step of the registration process of containers before sterilization, sterilizing, storage, placement and picking of sterilized containers, too. The Vertical Rotating cabinet, which has been developed specifically for storing containers and sets of sterilized items, is equipped with a touch-panel monitor for displaying stock status. The

monitor displays surgical operation-related information from electronic medical records in real time.

A staff member reads the surgical operation schedule from electronic medical records using a smartphone-type portable device. By scanning barcodes of such items as a patient ID and a surgical cart, the shelf automatically rotates and stops at the storage position of the necessary container. Read the barcode of the container to be used and store it in the operation preparation cart.

GLN (Global Location Number), which is a GS1 standard, is assigned as location information in the Surgical Center. They use GLNs for about 600 locations for shelves in the Vertical Rotating Cabinet and also some of the fixed shelves for accommodating small objects.
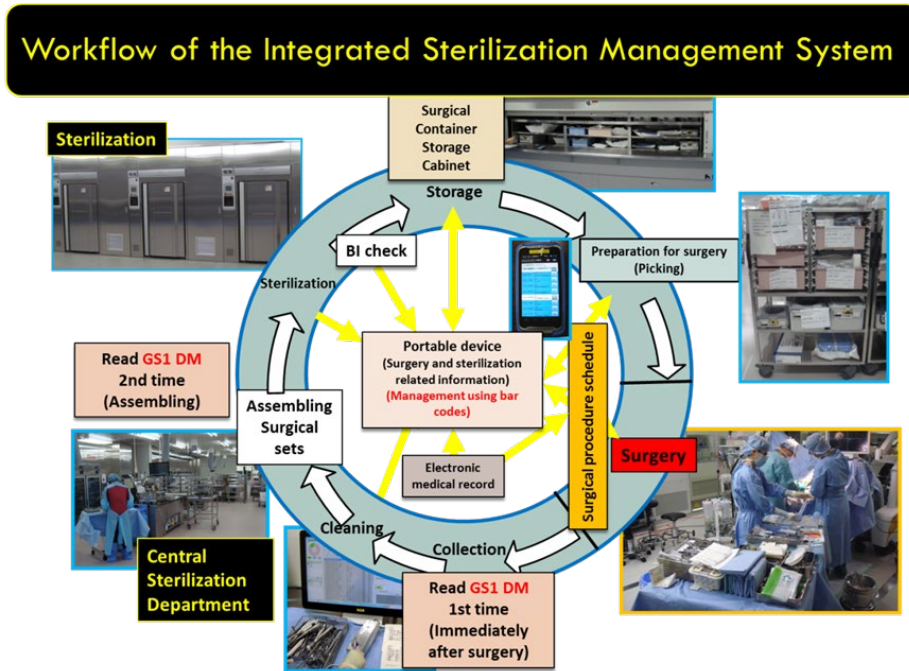
Fig. 3-4 Workflow of the integrated sterilization management system

(4) Effect of implementation

Specific benefits of the system include improved medical safety measures by ensuring traceability on individual steel instruments. This includes the prevention of leaving surgical instruments in a patient's body, the prevention of errors in counting, the more precise assembly of surgical sets, and the prevention of loss and unauthorized takeout. The system enables the hospital to more easily analyze the frequency of use or turnover as well as the status of stock instruments at specified piece and set levels. Furthermore, the analysis regarding the frequency of use by type of surgical method can help the hospital optimize the number and content of surgical sets.

Previously, experienced nurses had to assemble steel instruments in containers; however, this process became possible to be operated without these specialized skills and knowledge, and it was able to completely shift to the professional staff of the Central Sterilization Department. The assembly operation under this system is quick and accurate. The hospital estimates the system has also contributed to a reduction of approximately 2,000 hours annually for the overall operation time, including the confirmation of steel instruments after surgery.

In addition, container storage and picking tasks, part of the preparation process for surgical operations, have become automated, paperless processes based on the real-time status of sterilization stock. This changed the preparation time to one day from two days. It is estimated that the work time was reduced by 500 hours. By these benefits, nurses in the Surgical Center could concentrate on surgical operations and patient care, and it became possible to deal with the increase in operation numbers even when there was a shortage of personnel.

For cleaners, driers and sterilizers, the hospital has a system in place that provides the

operation status of each piece of equipment in real time through a monitor. This means that the cleaning and sterilization history along with the location and utilization history of instruments can be easily checked, thereby enabling the hospital to swiftly respond to a lack of instruments during surgery and recalls. It is expected that the analysis of instrument turnover in addition to their usage rate will further improve the efficiency of the operations.

References:
・ Kazufumi Sato, Yoko Ishimoto, Naomi Emori, Shingo Kasamatsu; Introduction and Operation of Integrated Sterilization Real-time Traceability System; The Japanese Journal of Medical Instrumentation, 86(3), 347-352, 2016
・ Kazufumi Sato, Shingo Kasamatsu; Introduction of Integrated Sterilization System and Its Usefulness, New Medicine in Japan, 43(9), 33-36, 2016

4	**Technical information**

As we have mentioned, Direct Marking is a generic name of
a) The technique of marking or printing two-dimensional barcodes or symbols directly on a product in a variety of methods
b) The technique of reading or recognizing Automatic Identification & Data Capture (AIDC) technologies for directly marked two-dimensional barcodes or symbols

The advantages of "less likely to fall off or missing colors," "unable to tamper," and "low running cost" are generally recognized. However, medical devices such as steel instruments and endoscopes have items to be noted, such as surface conditions, marking spaces, and the influence of surface deterioration due to, for example, exposure to high-temperature cleaning.

In addition, from the user's point of view, it may be preferable for both marking devices and readers to be easily introduced and to have fewer maintenance frequencies.

Marking equipment requires a function that maintains a readable printing state for a long period.

The barcode reader, which processes the images captured by the camera and decode the symbol, is required to enhance various image processing functions that reduce the effects of surface conditions and environment.

Both marking equipment and barcode readers have experienced technological innovations to improve above functions. Printing and scanning technologies are complementary to each other, and in terms of "enabling stable operation for a long period," it should be noted that the stable operation can be realized by improving both printing and reading functions rather than specializing in either of them.

In the following, each technology and related trends will be described in more detail.

1) Introduction to Printing Methods

(1) Laser marking
① Printing principle

Laser marking focuses a laser beam on the surface of a medical device, by discoloring or shaving the surface, to perform printing that can be identified by human eyes or AIDC technology. By scanning the laser beam with a scanning mirror, it is possible to print not only characters but also any information such as two-dimensional barcodes.
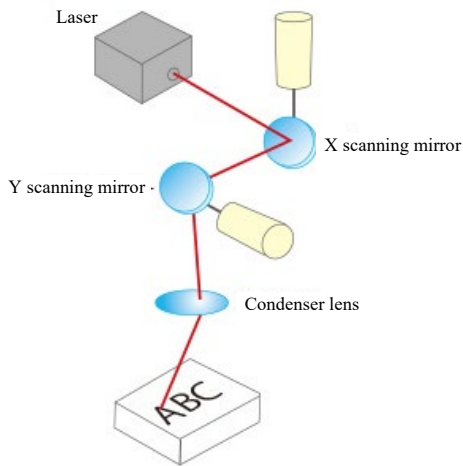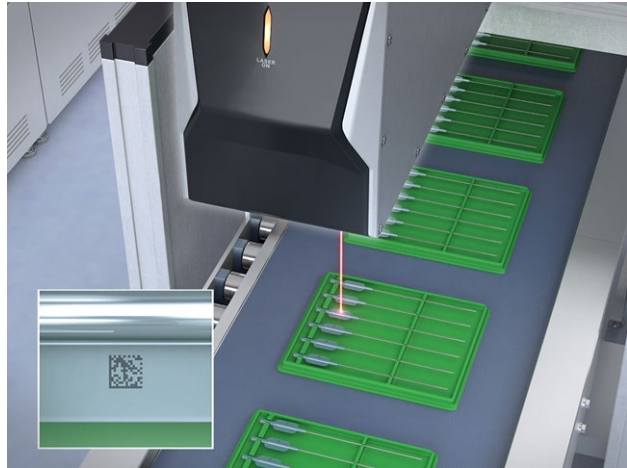

Fig. 4-1 Laser marker
conceptual diagram

Fig. 4-2 Example of laser marker
operation

Further, by changing the setting of the laser marking apparatus (laser output, converging diameter, etc.), it is possible to use a variety of marking methods. For metallic medical devices, the following techniques are used.

Black marking technique
    ---Technique to generate black color on the surface of an object by the heat of a laser
Engraving marking technique
    ---Technique to remove the surface by increasing the irradiation density of the laser beam
Cold marking technique
    ---Technique to develop black color leaving oxide film on the surface
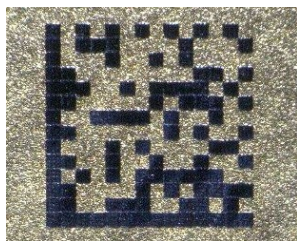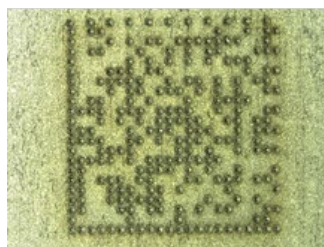
Black marking technique   Engraving marking technique   Cold marking technique

It is necessary to avoid rusting of the printed part due to long-term use in medical devices which are repeatedly used by performing cleaning and sterilization. It has been confirmed by experiments that the engraving marking technique and the cold marking technique are resistant to rusting. The optimum marking method should be selected considering visibility/readability by developing a black color.
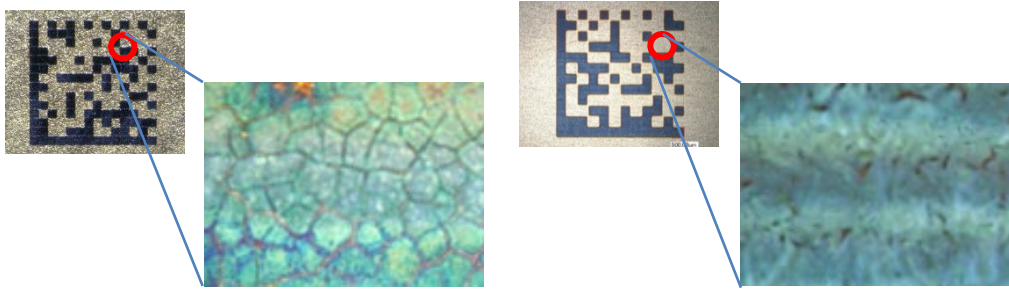
Fig. 4-3 Microscope magnification image (SUS)
Left: Black marking   Right: Cold marking

In cold marking, the oxide film of the stainless steel fractured by the printing is reformed, and the original corrosion resistance is recovered.

② **Advantages**
   Typical advantages of laser marking are as follows:
   ・ Contactless printing: It is possible to suppress damage to the product.
   ・ High-speed printing: High-speed scanning of laser beam allows printing on multiple products at a time
   ・ Fine printing: Small products and rod-shaped products can also be printed in narrow spaces.
   ・ Stepped part printing: A stepped area or on a semi-circle or other three-dimensional shape can be printed.
   ・ Ability to handle various materials: It is possible to print not only on metals but also on resin materials

③ **Minimum cell size**
   Fine spots can be realized in the selection of lenses for focusing laser beams. Printing by 0.5 mm × 0.5 mm square, for example GTIN and serial numbers printed by 26 digits (18 × 18 cells) in GS1 DataMatrix, is possible, although this small-size printing is not recommended in GS1 standards.

0.5 mm × 0.5 mm

1.0 mm × 1.0 mm

2.0 mm × 2.0 mm
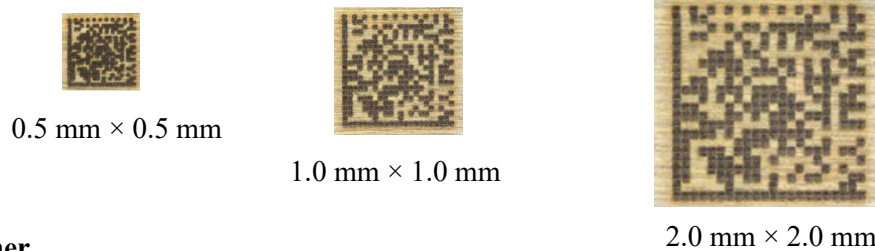
④ **Other**
   Due to the surface irregularities of medical devices, readings by automatic identification devices (readers) may become unstable. In such cases, the base, background, for printing GS1 DataMatrix can be made an even surface beforehand by laser to improve the read-stability.
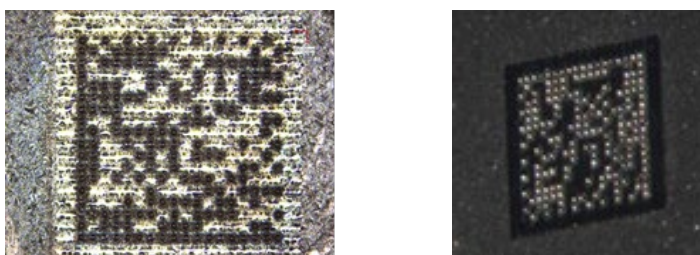
Fig. 4-4 Marking on evened base and image captured by a reading device

(2) Dot Peen marking
① Printing principle

Dot peen marking is a marking technique which is also called pin marking. Although this technology has been used in many industrial applications, it was regarded as low quality and an unsuitable method for medical device marking which requires strong and precise marking. However, recently, equipment which enables high-precision and high-definition marking has come on the market, exclusively for marking for medical devices. This chapter describes high-precision dot-peen marking devices developed specifically for medical devices.

The equipment has a very small component, called a stylus, with an artificial diamond embedded in the tip. The targeted material surface is dented by the stylus, resulting in a succession of visualized figures with light reflection change. In addition, the control of the dot size is also possible by the adjustment of the stamping pressure.
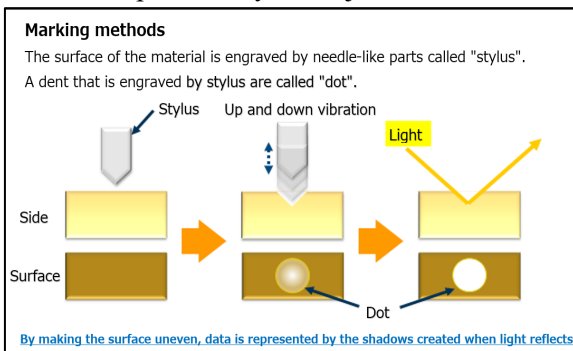
Fig. 4-5 How to mark dot pins   Fig. 4-6 How to control dot shape
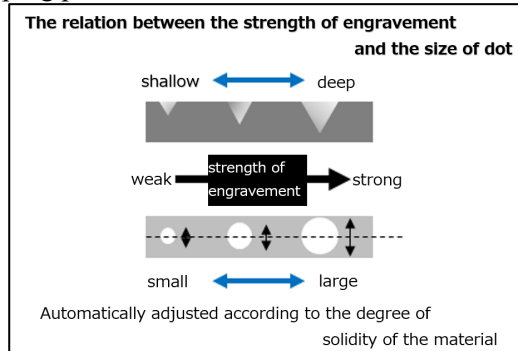
Various two-dimensional barcodes as well as alphanumeric characters, logo marks and figures can be expressed with high precision and high definition (Figures 4-7, 4-8). Since the shape of the material surface is changed but not be colored on the surface, color missing due to aging or falling off of the marking site does not occur. Marking objects correspond to metal materials such as aluminum, brass, copper, stainless steel and titanium.
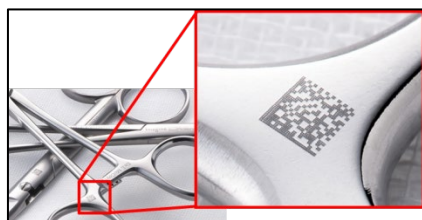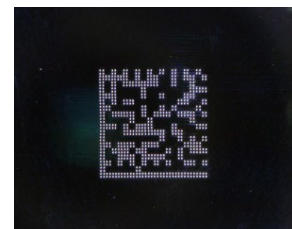

Fig. 4-7 Example of character logo

Fig. 4-8 Two-dimensional barcode   Data Matrix (rectangle)   Data Matrix (square)

② 1-mm-square 2D symbol and character can be marked

For marking of medical devices, data composed of GTIN and the serial number in GS1 DataMatrix is recommended to be directly marked on the surface of the medical device, with a square of 3 to 5 mm or a rectangular of about 1.2 × 3.6 mm to 1.5 × 4.5 mm.

Though these small sizes could only be marked by the laser marking equipment before, the marking is possible nowadays if high-precise dot peen equipment is used. More small sizes, for

example, 1 mm × 1 mm is also possible, though this small size is not practical because the engraved position cannot be confirmed visually and applicable readers are limited (Figure 4-8).
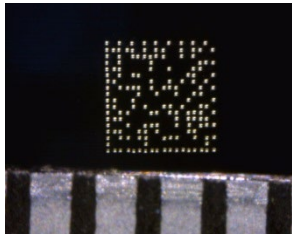

Fig. 4-8 Marking of 1.0 mm × 1.0 mm (Scale: 0.5 mm)

③ **The number of dots constituting the cell**

In high-precision dot-peen technology, it is also possible to mark two-dimensional barcodes by changing the number of dots per cell (Figure 4-9). For two-dimensional barcodes, the number of cells comprising symbols varies depending on the data to be encrypted. By utilizing this function, optimal marking can be made for the size of the symbol.
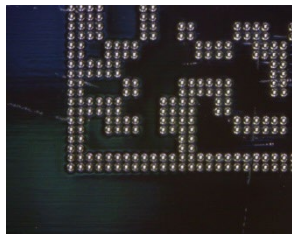
Fig. 4-9 Marking 1 cell with 2 × 2 dots　　　　　　　Marking 1 cell with 1 dot

④ **Size and space of each dot**

Dot peen technology expresses two-dimensional barcodes in the shape of dots. Therefore, if the size of the dot cannot be controlled, dots interfere with each other when the output power is low; conversely, dots are too far apart when the output is high. If the size of the dot or the distance between dots cannot be controlled, only a certain size can be marked. The high-precision dot peen marking device automatically controls the size and distance of the dot according to the size of the symbol and the material to be marked (Figure 4-10). Thus, it is possible to perform optimal marking according to the output size and material hardness.
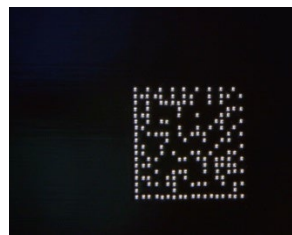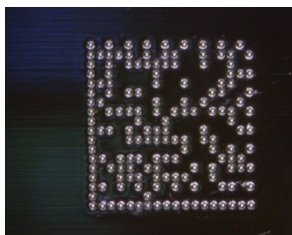

Fig. 4-10 Two-dimensional barcodes with different output sizes for 1 cell with 1 dot
Automatically adjusts the size of the dot and the distance between dots.
(Photos are taken at the same magnification.)

⑤ **Special features**

・ **Highly practical marking with excellent durability and corrosion resistance**

The marking results of the dot peen method are strong against abrasion because the concave portions are deep, and there is no rust caused by marking (Figure 4-11). It has already been used in many facilities, and it has been confirmed that the readability is well. It has been proved that there is sufficient durability and marking quality for actual use.

・Marking without sacrificing the function of the material

The dot peen method is more likely to give an image that is strongly marked by air driving, but the high-precision dot peen marking device can be used in a 100V power supply for household use, and it is unnecessary to prepare an industrial power supply, air piping, etc. It has the necessary and sufficient ability to mark high-definition characters, logo marks, and two-dimensional barcodes for medical devices mainly those made of stainless steel (Figure 4-12).

Fig. 4-11 Example of marking after
24-hour salt spray test

Fig. 4-12 Marking example
No loss of product function

・ Operated by anyone

Since it is assumed that only metallic medical devices should be marked, adjustment is almost unnecessary. The main unit of the equipment has only two On/Off switches, a power supply and a laser pointer for positioning. The simple equipment does not confuse workers when it is used at intervals. In order to ensure the safety of the work, the operating parts are covered and there is a safety system that can be operated safely and easily by anyone.

・ Stable, worker-independent marking

The main unit is only equipped with a function to adjust the marking point and the height is adjusted automatically. Although the adjustment of the output is performed using dedicated software, any difference between workers does not occur because the setting condition is recorded. Even a first-time operator can operate it for as long as 30 minutes.

・ Space saving

The body size is also small and can be installed in a space 30 cm × 40 cm. Since it is a space-saving design, it can be installed in the office of a central sterilization department in a hospital. In addition, since it does not generate loud noises, vibrations, or strong light at the time of marking, workers can use it safely with low stress.

⑥ **Points of caution**

・ Marking time

It takes about 30 seconds for marking a 3 mm square two-dimensional barcode, though the time varies depending on the data contents and marking method. Dot peen marking is effective for marking a large variety of small lots of medical devices, however, laser marking may be more effective when marking large quantities of the same type of materials.

・ Marking object is metal only

Since the dot peen method is a technology to express symbols by adding irregularities to the marking surface using a stylus, a certain degree of hardness and deformability are required for the material. Therefore, it is unsuitable for marking on glass and rubber materials. Although marking on resin materials is possible, there are problems with visibility and durability, so it is not recommended.

⑦ **Others**

・ Scanning by a barcode reader may become unstable due to surface irregularities of medical devices.

・ The marking on the cylindrical shape is required to align the center of the equipment with the

center of the marking.
・ In the case of marking on painted products, the painted surface may peel off.
・ It has been confirmed in the operation that the marking on the plated product does not affect the plated part. However, this does not apply when the plated state has deteriorated over time.
・ In the actual operation, it is necessary to decide the print size by carrying out verification work such as a consistency test with the barcode readers.

2) Reader Introduction

Since GS1 DataMatrix, the two-dimensional barcode, is defined as the standardized barcode for marking on steel instruments, this chapter mainly explains the two-dimensional barcodes reader (hereinafter referred to as the reader).

(1) Type of reader

The reader can be classified into three types: desktop reader, fixed reader, and handheld reader.

① **Desktop reader**

Desktop reader is sometimes encompassed in fixed readers, but it is explained as an individual category here, because the operation style is different especially in the steel instruments application. A desktop reader is placed on a desk or a work table and a person holds the medical instrument to be read.

② **Fixed reader**

Fixed readers are used to read specific symbols automatically on the objects transported on production lines, logistic bases and so on. Because special lighting (light source), lenses, etc., can be selected according to the reading environment, a wide range of readings is available.
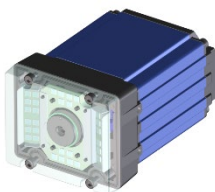
③ Handheld reader

Handheld readers are a type in which an operator holds a reader in his/her hand and reads a symbol on an object. Common handheld readers are inexpensive and easy to obtain, but unfortunately cannot read steel instrument markings. Although there is a handheld reader that can be used for steel instrument markings, it is recommended to consult with the reader manufacturer because it may be a special device.
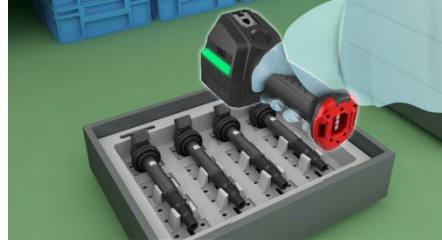
(2) Precautions for Reading Direct Marking of Medical Devices

Although the performance of barcode readers has improved year by year, Direct Marking of medical devices requires caution in reading compared with barcodes printed on general labels.

The reasons are generally classified into three categories.

① Marking Size

Steel instruments have limited marking space and two-dimensional barcodes must be printed very small. A high resolution camera, which can read even small-size marking, is required.

② Contrast

As the method of Direct Marking has been explained in the previous chapter, since it is a method of printing directly on the object, the base color of the symbol to be printed varies depending on the material of the object.

It is necessary to devise ways of lighting so that the contrast, light and dark, is clear, because it is not printed in black and white as with usual labels.

③ Surface condition

Similar to the description in the previous contrast, Direct Marking is performed on a variety of base materials such as mirror surface, matte and satin depending on the materials. Since the marking surface may also be curved, it is difficult to image cleanly if taken in a normal way. It is necessary to devise a method for the camera and lighting conditions.
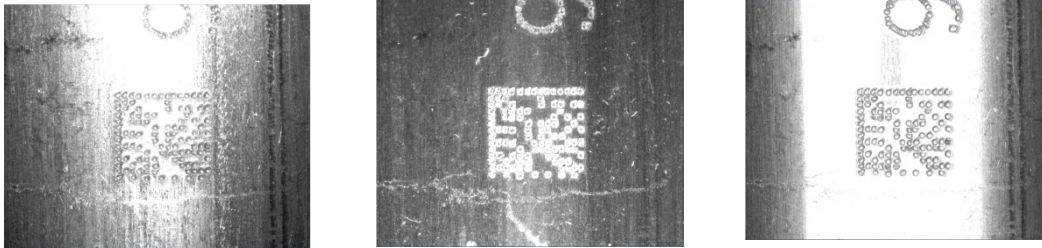
(3) Function for stable reading of steel instrument markings

In order to read the Direct Marking stably, the following functions are effective.

① Lighting Selection

It is possible to acquire the image which is easy to read by way of illumination (color, angle, etc.).

Image example)

Illumination without polarization   Illumination with polarization   Dome illumination

※ The objects are the same, and the types of lighting are different.

② Image correction

It is a function to correct the acquired image for the object with inferior marking quality. Stable reading can be performed by processing image correction, such as filling extra space or enhancing contrast.

Image processing example)

No image-processing   →   Black expansion + Contrast enhancement; black

No image processing   →   De-noising base + Contrast enhancement; white

③ High-resolution camera

Since Direct Marking of medical devices is assumed to be printed in a very small size, a high-resolution camera, which can read even small cells, is required. High-resolution cameras to read small print mostly require contact readings.

Regarding the selection of readers for Direct Marking, it is recommended to consult with marking equipment manufacturers and let the manufacturers carry out preliminary reading checks, because the readability of each model is different depending on the marking quality of the object.

5. Reference materials

List of companies in Japan providing marking devices or barcode readers

Company name and Website	Marking device		Barcode Reader		
	laser	dot peen	desk-top type	fixed type	handheld type
ID LASER CORPORATION https://www.id-laser.co.jp/en/index.html	●			●	
IDEC AUTO-ID SOLUTIONS Corporation https://ias.co.jp				●	●
AINIX Corporation https://www.ainix.co.jp				●	●
KEYENCE CORPORATION https://www.keyence.co.jp	●			●	●
Cognex Corporation https://www.cognex.com				●	●

Company name and Website	Marking device		Barcode Reader		
	laser	dot peen	desk-top type	fixed type	handheld type
KOBAYASHI Kobayashi Create Co., Ltd. https://k-cr.jp					●
Sakura System Solution Sakura System Solution Co., Ltd. https://www.sakura-sl.com	●	●	●	●	
TCODE Terrara Code Reserch Institute. Inc. http://tcodes.jp					●
DENSO **DENSO WAVE** DENSO WAVE INCORPORATED https://www.denso-wave.com			●	●	●
Touou Electric Co.,Ltd Touou Electric Co.,Ltd https://tououdenki.com			●		
MICRO-TECHNICA MicroTechnica Co., Ltd. https://www.microtechnica.co.jp			●	●	●

Company name and Website	Marking device		Barcode Reader		
	laser	dot peen	desk-top type	fixed type	handheld type
MTS MARS TOHKEN SOLUTION MARS TOHKEN SOLUTION CO.LTD. https://www.mars-tohken.co.jp				●	●
MIZUHO Medical Innovation MIZUHO Corporation http://www.mizuho.co.jp	●		●	●	●
MKI MITSUI KNOWLEDGE INDUSTRY MITSUI KNOWLEDGE INDUSTRY CO., LTD. https://www.mki.co.jp/english/		●	●		●
Something to Life **METS** METS INC. https://www.mets-tokyo.jp			●		

Operation Guide for Direct Marking on Medical Devices

ver. 2.6

September 2024

Edited by: GS1 Healthcare Japan