Evolution for patient safety using laser marking on surgical instruments in Japan

Report on the verification of the instrument traceability system at Osaka University Hospital and example of system implementation at another health care institution

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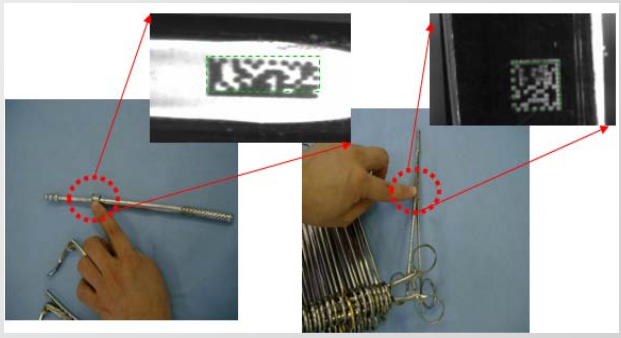
Verification of direct marking of DataMatrix barcodes on surgical instruments -1-

In October 2005, we started to mark two-dimensional DataMatrix barcodes directly on the surgical instruments for laparotomies in the Department of Obstetrics and Gynecology. Direct marking was expanded to endoscopic equipment in the Department of Urology in June 2006. And then we conducted verification on the practical performance of our surgical instrument traceability system featuring the sterilization management function using the DataMatrix barcode symbology.

Surgical instrument set for laparotomies in the Department of Obstetrics and Gynecology



Endoscopic equipment set in the Department of Urology

DataMatrix barcode

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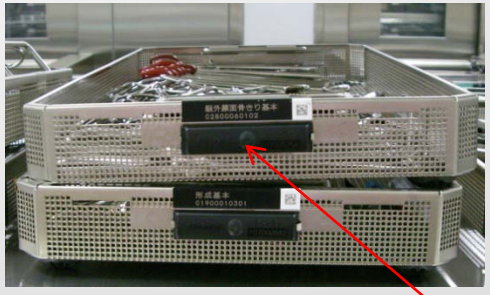
Verification of direct marking of DataMatrix barcodes on surgical instruments -2-

For containers and inner baskets of sterilization devices, we have developed heat-resistant metal-compatible RFID tags.
We have also conducted verification on the practical use of these newly developed RFID tags. Verification included a durability test.



Our newly developed heat-resistant metal-compatible RFID tags

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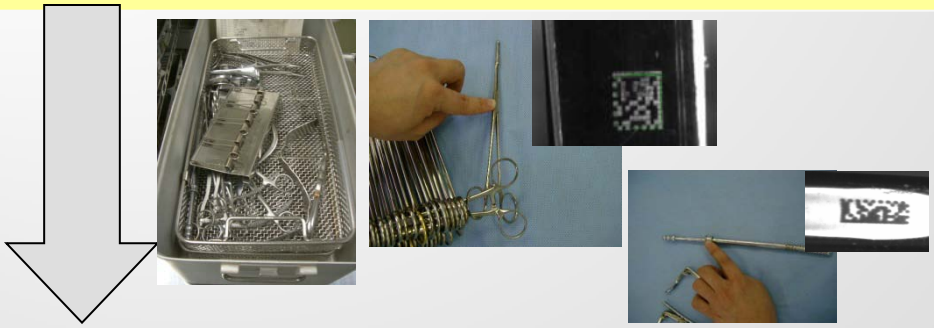
Challenges faced before implementation

- Establishment of effective measures against discoloration of copper instruments due to cleaning
- Realization of smaller DataMatrix barcodes to suite the reading capability of the reader
- Verification of the reading capability of the hand-held reader for DataMatrix barcodes attached to containers



Fields other than the obstetrics and gynecology for implementation of the system were under review at that time, and to resolve the above problems **a new reader has been developed** since 2005 and **the smallest symbol size of 0.8mm has been validated** at the same time.

Report on Practical Use (Application and Engraving Method)

- Laparotomy container for Obstetrics and Gynecology: 5sets
- Surgical instruments per container: 88 items
- 5 Containers × 88 instruments = 440 instruments under serial number management
- Structure of DataMatrix marked on surgical instrument

Structure of DataMatrix : 【16 digits】

FNC1+90+Hospital (5) + 21+ Consecutive numbers(7)

GS1 Application Identifier 2 digits
hospital
serial number

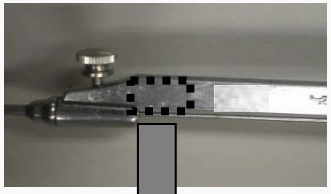
9 0 : assets owned by the
2 1 :

■Engraving pattern

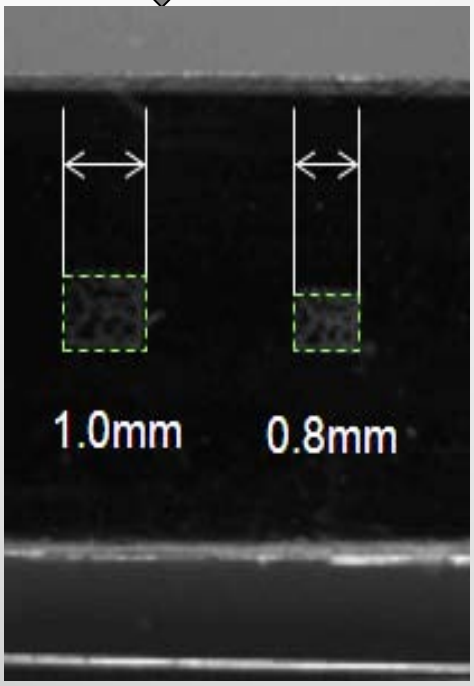
①2.5mm×2.5mm ②1.2mm×2.7mm ③1.0mm×1.0mm

④0.8mm×0.8mm

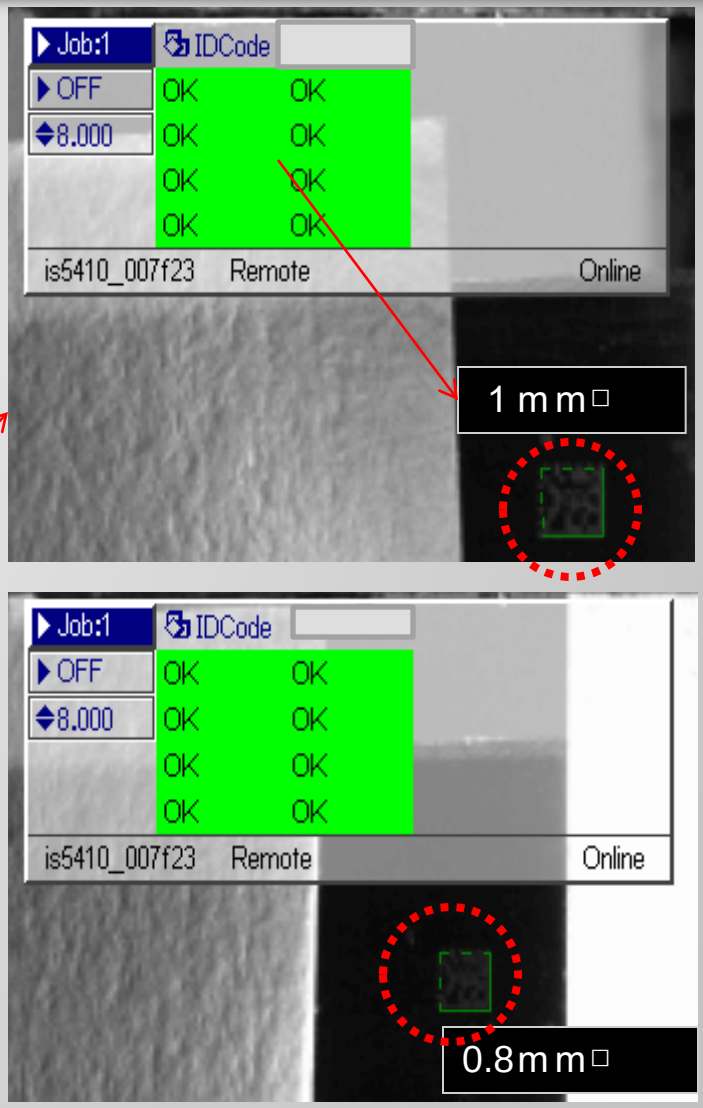
Validation of smallest engraved symbol size readable with the new reader



Engraving: White-line engraving
Numeric : 16 digit writing



Capable of reading without adjustment from 5mm□ to 0.8mm□. Reading time (0.4 sec./instrument)



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Development of DataMatrix Symbol Reader

To permit the reading of symbols engraved to a size of about 1mm, a high-performance. camera was used. The lighting used was of the direct exposure type that highlights the engraved symbols on discolored copper instruments. The system was developed on the condition that is reading also the 0.8mm □ ~ 2.5mm□ and 1.2*2.7mm symbol sizes used at the Osaka University without software and lens adjustment.

Camera spec.

Firmware	
Memory	
Job/ Program	16MB non-volatile flash memory, When using the remote network device, no limitation for storage.
Image processing	64MB
Image	
Sensor	1/3 in. CCD (5.84×4.94 mm, diagonal: 6mm
	640x480 pixel display (307,200 square pixels, 7.4 x 7.4μm)
	Electronic shutter speed: 32 micro-sec. ~ 100milli-sec.
Image intake	Rapid reset, progressive scan, full-frame integral
	256 step adjustable gray level (8 bits/sec.)
	Gain/offset control via software
	60 Frames per second
Lens type	C mount

Assessment by image intake under external trigger 1 time per 0.1 sec. Range of view 20mm □

External view of developed unit

HN-06-16MType (Direct Exposure type) manufactured by M- Next

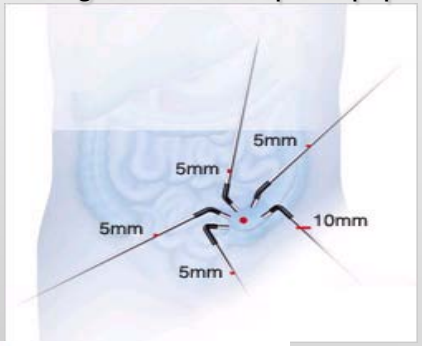
Verification of direct marking of DataMatrix barcodes on endoscope components

We conducted another verification on the practical performance of our traceablitity system for endoscope components in the Department of Urology. First, we selected four types of components in common shapes which are made of widely used materials. On those components, DataMatrix barcodes (16 Bytes of alphanumeric characters) were directly marked by a YAG/YVO4 laser machine, of which a reading verification was performed.

The reading verification proved that the laser marked DataMatrix barcodes could be read by our hand-held reader without any problems. For stainless-steel components and titanium alloy components, DataMatrix barcodes with a size of 0.96 mm by 2.08 mm (0.0377 in by 0.0818 in) were marked by the YAG laser machine,, for black plastic components, DataMatrix barcodes with a size of 1.8 mm by 3.9 mm (0.0708 in by 0.1535 in) were marked by the YAG laser machine. For non-black plastic components, DataMatrix barcodes with a size of 3.2 sq. mm (0.1259 sq. in) were marked by the CO2 laser machine.

DataMatrix barcodes with sizes indicated above were additionally marked on all endoscope components including optical videoscopes, codes, loop electrodes and biopsy forceps owned by the Department of Urology. By using those endoscope components with DataMatrix barcodes for operations in the Department of Urology, we evaluated the feasibility of introducing the instrument usage traceability system.

Surgical Endoscope Equipment



Laparoscopic Surgery

Videoscope

Urology Instrumentation

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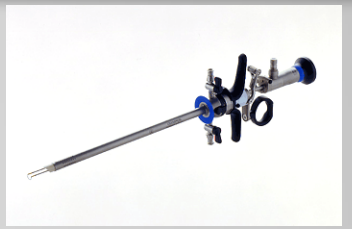
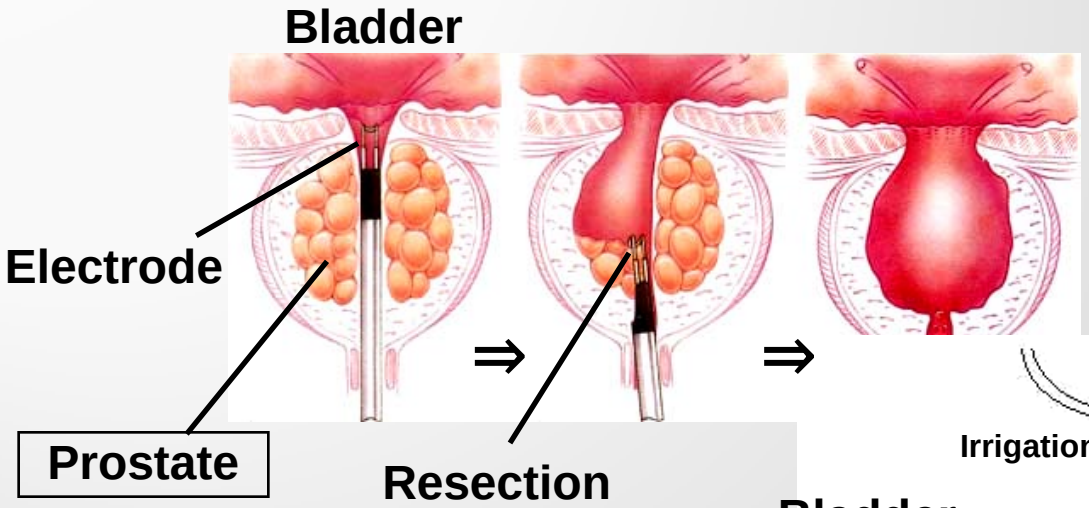
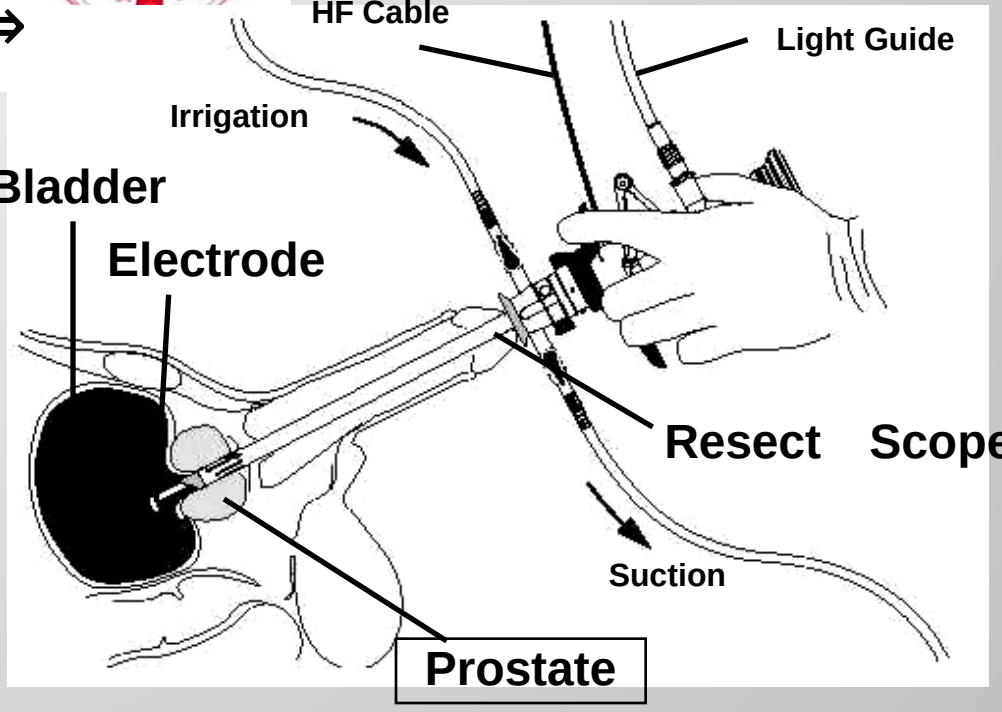
TUR-P Transurethral Resection of Prostate

経尿道的手術（TUR）







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Why is selected Resect Scope for traceability?

◆Instrument utilized a lot of parts for various shape and size

⇒ Troublesome preparation and maintenance

About 30 parts / set

↑Autoclavable items

Camera Head

EOG or Plasma sterilization →

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Direct marking on instruments(Plastic parts)

- Preferred symbol locations

①Near the product logo

②Flat surface for better readability

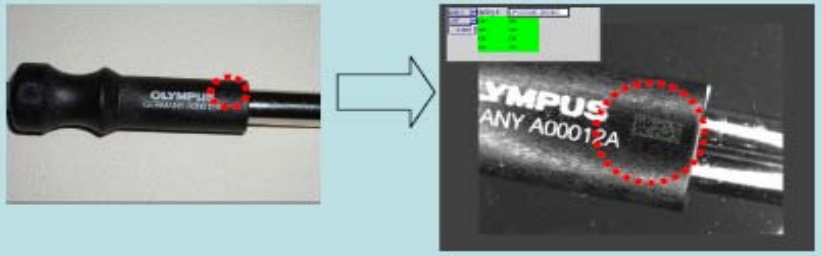
DataMatrix

Laser etched

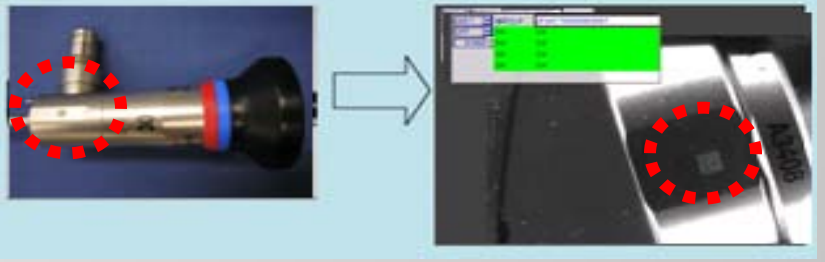
③Space with enough quiet zone

- Verification of readability

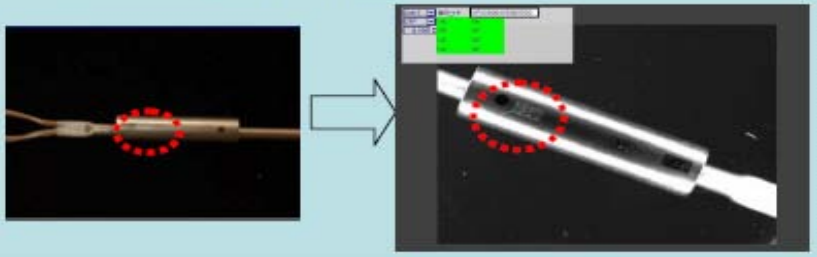
1.8 × 3.9mm□ 16Byte **Plastic (black)**



1.0mm□ 16Byte Titanium Alloy



0.96mm * 2.08mm□ 16Byte Φ4 SUS



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Verification of heat-resistant metal-compatible RFID tags for sterilization devices -1-

In the management of surgical containers, since the amount of information to be handled is large, heat-resistant metal-compatible RFID tags that allow automatic reading from stacked containers are suitable.

To meet these needs, we have developed a new RFID tag (metal-compatible electronic tag: 2.45GHz, storage temperature 95 ° C) coated with heat-resistant resin (with heat resistance up to 165 ° C.) With this new RFID tag, after 500 times of high-pressure steam sterilization (135° C, 15 minutes, drying 40 minutes), all of the 110-byte internal data was correctly read without any problems.

	Number of times of sterilization	RFID tag ready for sterilization	Results
High-pressure steam sterilization (135°C)	5 0 0		After 500 times, the data could be read without any errors.

Sterilization process during the heat-resistant test
Preheating: 10 min.
Vacuum pulse: 3 times
Sterilization: 15 min. at 135 ºC (275 ºF)
Drying: 40 min.

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Conclusions

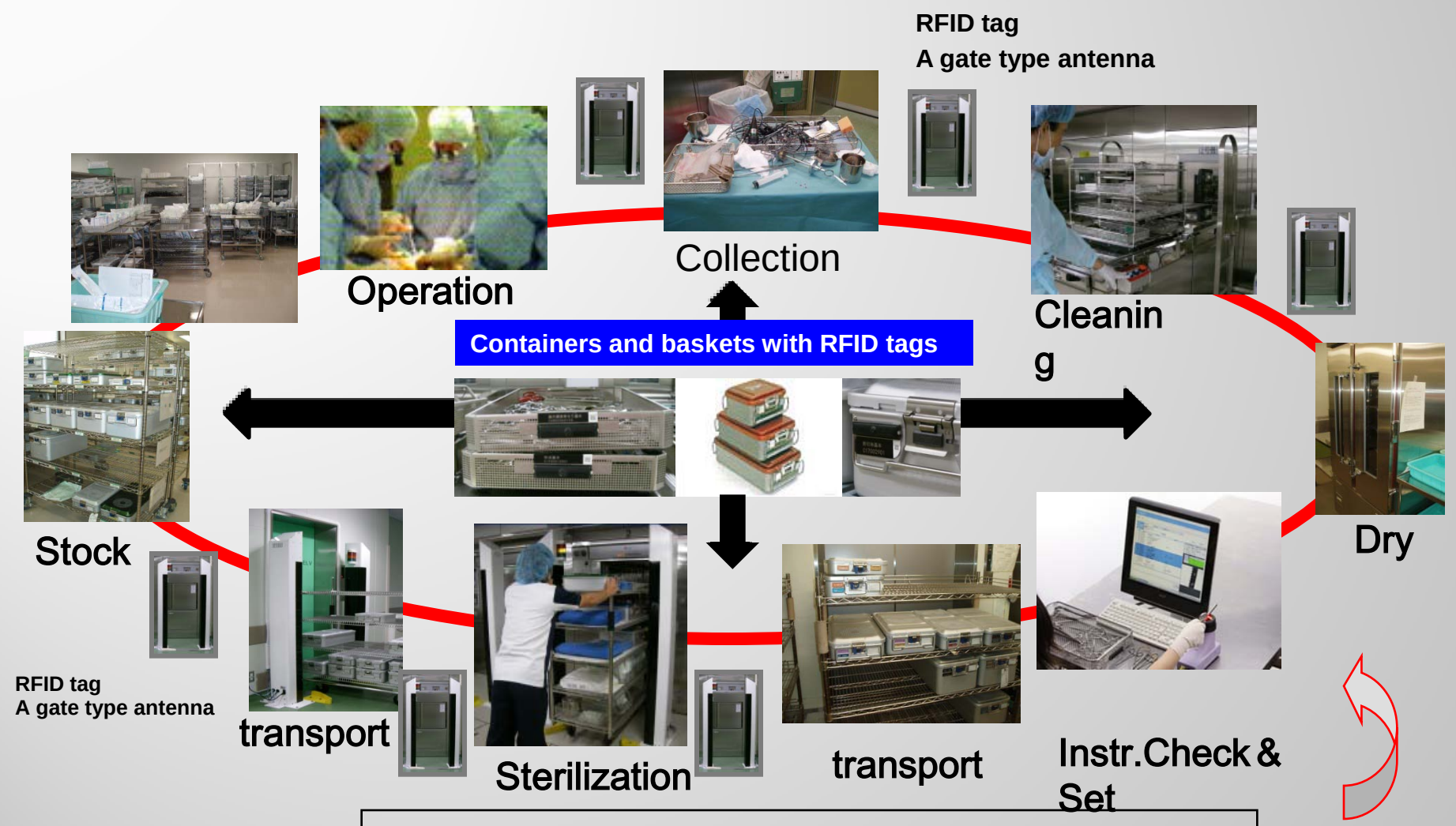
- The time required to read the DataMatrix barcodes marked on eighty-eight surgical instruments in one instrument set tray was between 5 and 7 minutes including the time required for human action, which is short enough for practical use.
- In the Operation Department, DataMatrix barcodes with sizes of 2.5 mm by 2.5 mm (0.0984 in by 0.0984 in) or 1.25 mm by 2.7 mm (0.0492 in by 0.1062 in) were directly marked on the surgical instruments. When we conducted the verification for the endoscopic equipment, DataMatrix barcodes with sizes as small as 0.8 mm to 2.5 mm (0.0314 in to 0.0984 in) were marked and read. The result of verification indicated that the data traceability system was practical for actual operation, thanks to the successful development of our new barcode reader.
- After two years of practical use, we conducted a follow-up reading verification, which revealed that all the data encoded in the DataMatrix barcodes could be read without any errors. No deterioration such as corrosion or rust in the marked DataMatrix barcodes was observed.
- All the data encoded in the sterilization-resistant RFID tags was successfully read without any problems after 300 times of sterilization, which validates the durability of sterilization-resistant RFID tags.

Examples of system implementation at another health care institution based on the previous verifications

- **Hospital capacity**
  880 general beds and 30 exclusive beds for patients with infections
- **Number of operating theatres**
  15 operating theatres (including 5 exclusive operating theatres for infectious diseases)
- **Number of surgical instruments owned by the hospital**
  Approximately 100,000 instruments
  (markable surgical instruments only)
- **Equipment used in operating theaters and central supply department**

3 steam sterilizers
2 EOG sterilizers
2 plasma sterilizers
2 sets of automatic cleaning machines
6 manually-operated cleaning devices
2 drying machines

Instrument Cycle



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Sterilization Guarantee and Tracing System

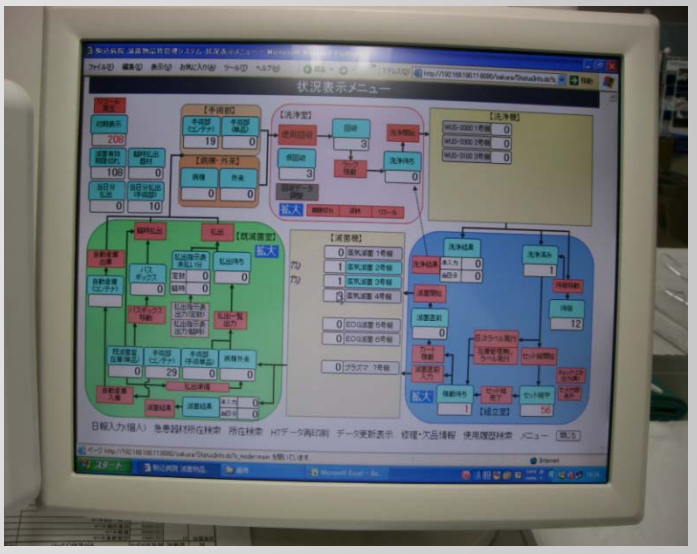
(Functions)

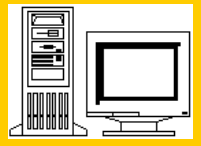
- Fully integrated control through the network
- Document preparation and data management
- Support for set array (Automatic deletion entry with detailed data)

- Location control of sterilized items
- Valid terms management for sterilization
- Control of use and sterilization records

- Fixed-number control
- Cooperation in ordering & checking function

A total state indication screen





Surgical Instrument Management Database

- Item data
- Set array data
- Maintenance data Repair and Contractor Management
- Surgical data
- Container data
- Cleaning data
- Sterilization data
- Container and equipment analysis data

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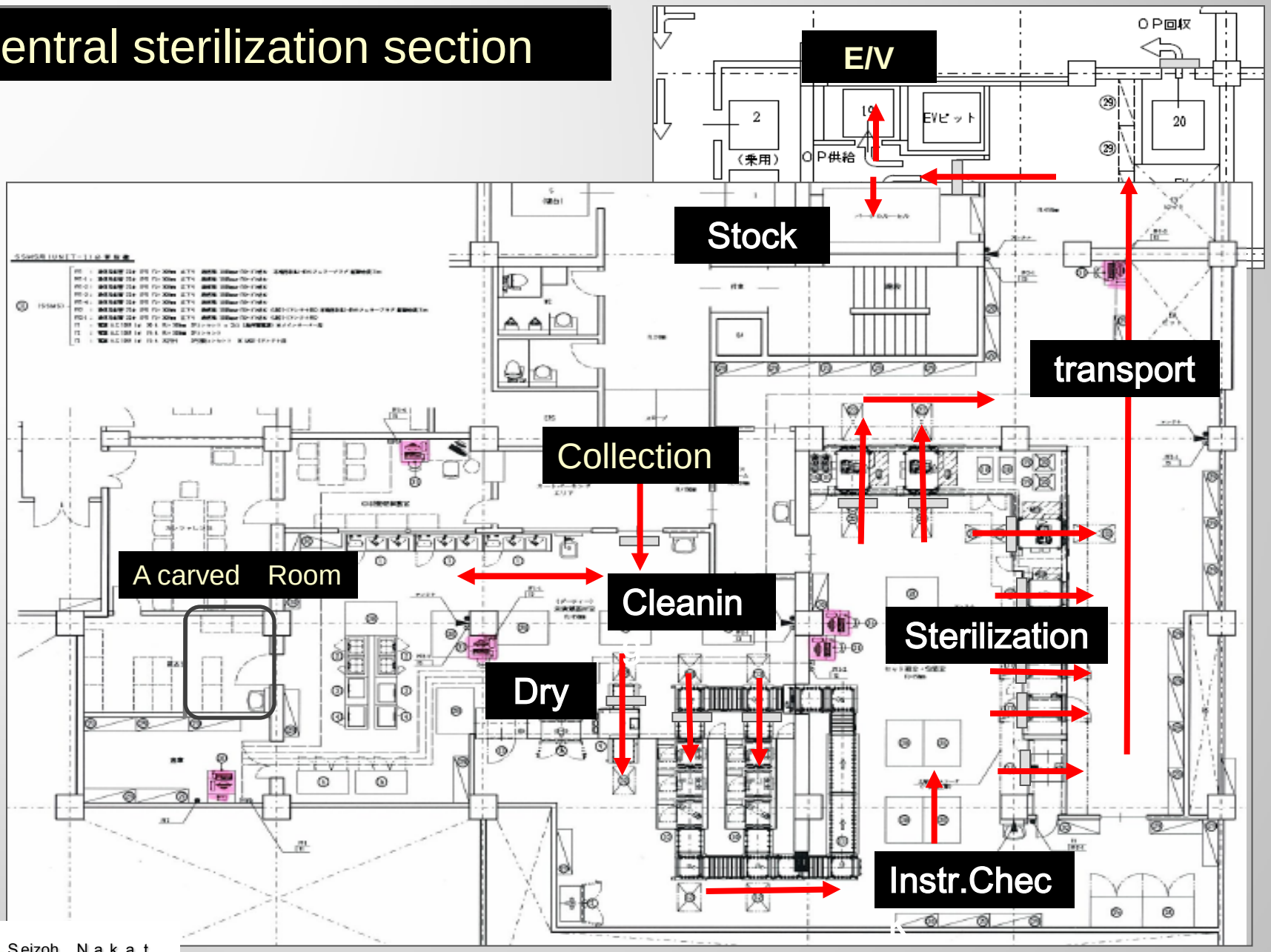
A central sterilization section



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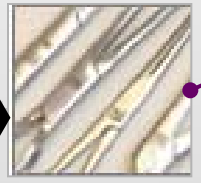
Data traceability system using DataMatrix and RFID tags

Gate type antenna

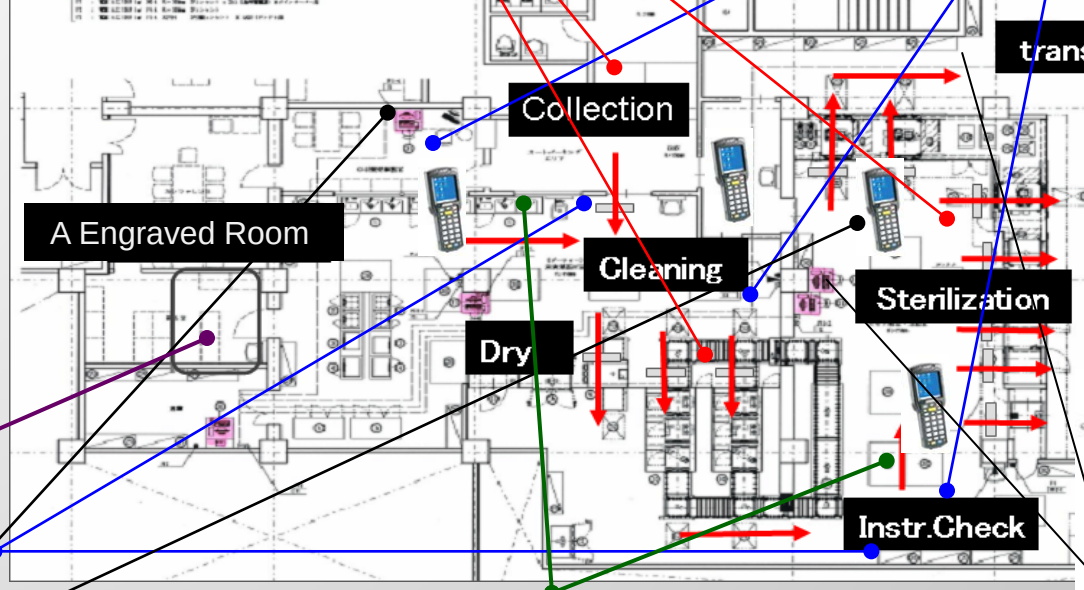
Gate type antenna*14 units

RFID TAG

Engraved on the surgical instruments



Hand-held terminals*5 units



DataMatrix reading system*10 sets

5 Antennas for Spread-Spectrum System*5 units

Marking technologies -1-

DataMatrix barcodes with encoded data of 16 bytes, FNC1 + 90+ hospital code + 21 + serial number, were marked directly onto the 100,000 surgical instruments owned by the hospital. Based on the sizes of the DataMatrix barcodes, the marking technology was selected between dot marking and laser marking. For DataMatrix barcodes with sizes of or larger than 3.2 sq. mm (0.1259 sq. in), micro-percussion machines were used. For DataMatrix barcodes with sizes between 0.8 sq. mm and 2.5 sq. mm (0.0314 sq. in and 0.0984 sq. in), laser marking machines were used.

	Advantages	Disadvantages
Dot-marking machines	Marking depth is deep. High scratch resistance. Takes only a short time. (2 DataMatrix barcodes at two locations can be marked within 20 seconds)	16 Bytes DataMatrix barcodes with sizes smaller than 3.2 sq. mm may become unstable.
YAG/YVO4 laser-marking machines	Marking depth is deep. High corrosion resistance. Can make the size of the DataMatrix as small as 0.8 sq. mm to 2.5 sq. mm.	Marking depth is shallow. Susceptible to scratches. Takes a longer amount of time. (2 DataMatrix barcodes at two locations requires approximately 60 seconds.) Needs non-scratch-prone surface for marking.

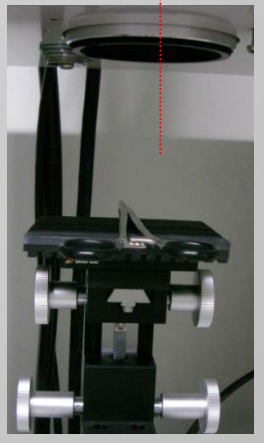
Marking technologies -2-

Dot-marking machines

Medrix by Technifor

YVO4 laser-marking machines

KEYENCE



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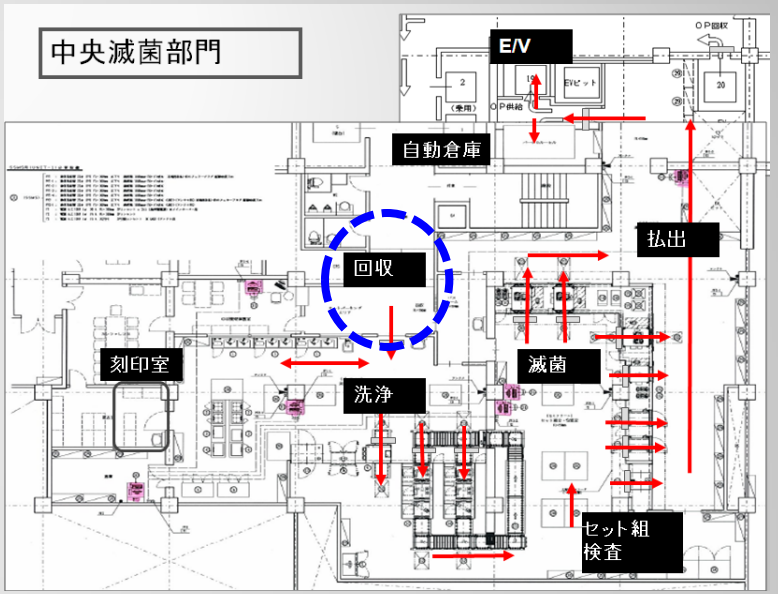
Collection

Each time when the inner baskets or sterilization containers with RFID tags pass through the gate-type antenna, the encoded data is automatically tracked, recording the information on the collected baskets or containers.



Gate-type antenna at collection points

Carts for collection and RFID tags attached to inner baskets and containers

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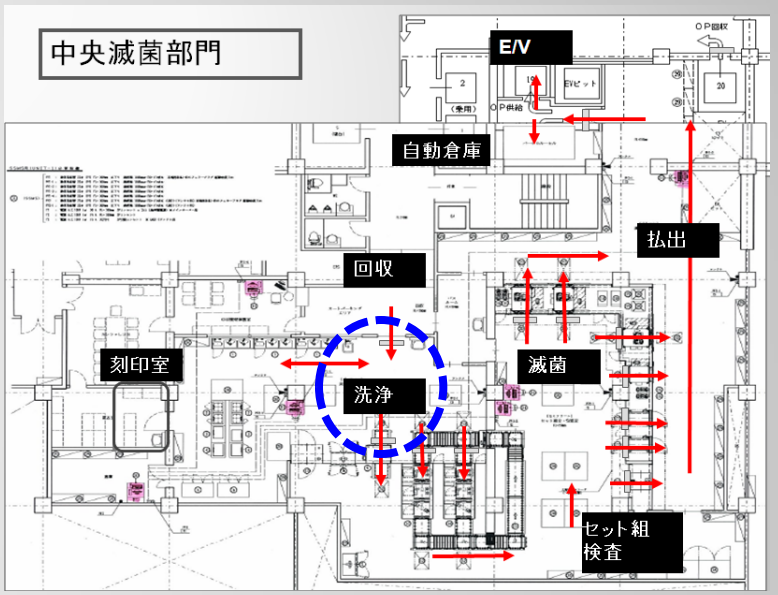
Cleaning room

Before and after cleaning, the antenna automatically reads the encoded data of RFID tags attached to the inner baskets of cleaning machines. This data, which is linked to each cleaning machine, is transferred as a cleaning record of each inner basket.



RFID tags attached to inner baskets of a cleaning machine

Gate-type antenna to read RFID tags for multiple tank automatic cleaning machine

Gate-type antenna to read RFID tags for single tank automatic cleaning machine

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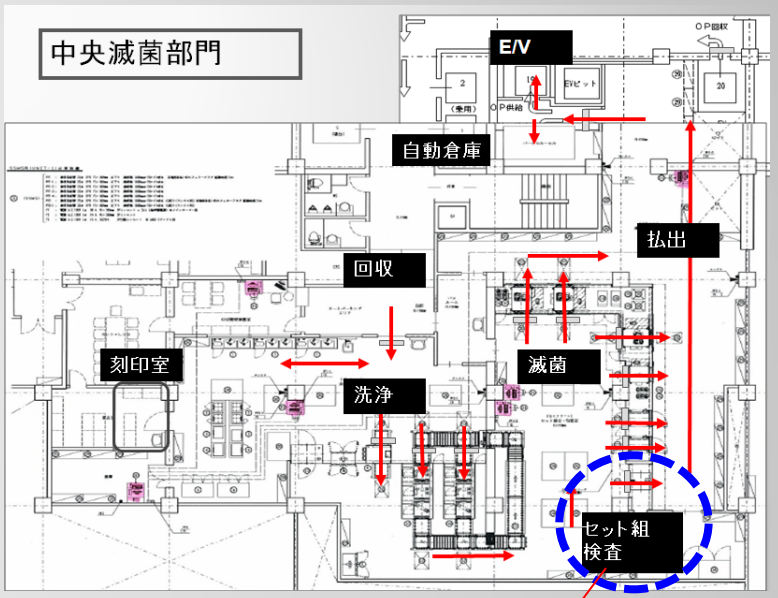
Instrument set assembly

The number of surgical instruments for operating theatres, endoscopic equipment and other medical instruments used in the hospital ward is 100,000.



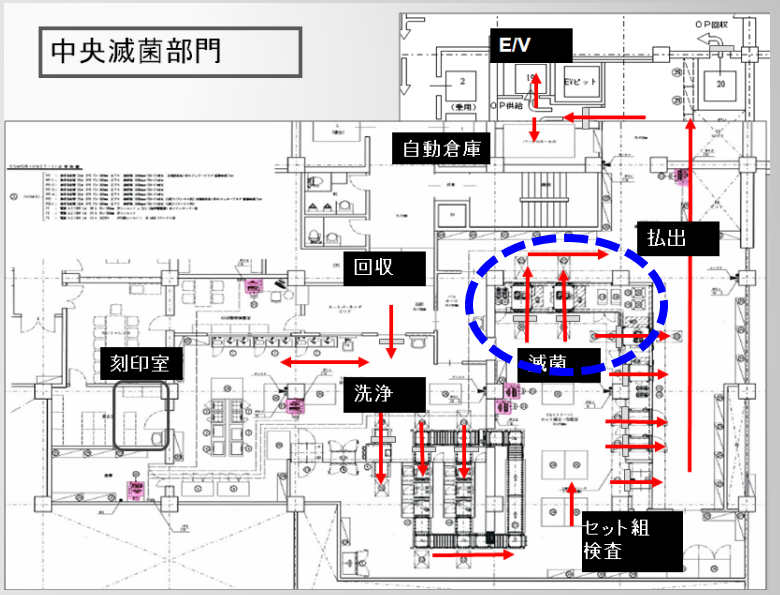
Sizes of DataMatrix barcodes (mm)

Square symbols		Rectanglar symbols	
Symbol sizes	Data capacity in alphanumeric characters	Symbol sizes	Data capacity in alphanumeric characters
0.80 x 0.80	16	0.96 x 2.08	16
1.20 x 1.20		1.14 x 3.42	
1.92 x 1.92		1.62 x 2.10	by YVO4 laser-marking machine
2.40 x 2.40			
3.20 x 3.20	by dot-marking machine		

Instrument set assembly using direct marking technology

Sterilization

Before and after sterilization, the antenna automatically reads the encoded data of the RFID tags attached to the sterilization carriages or containers. This data, which is linked to each sterilizer, is transferred as a sterilization record of each container. For the packages or bags to which the RFID tags cannot be attached, hand-held readers are used to scan the printed barcodes on the label, which is also linked to each carriage number.

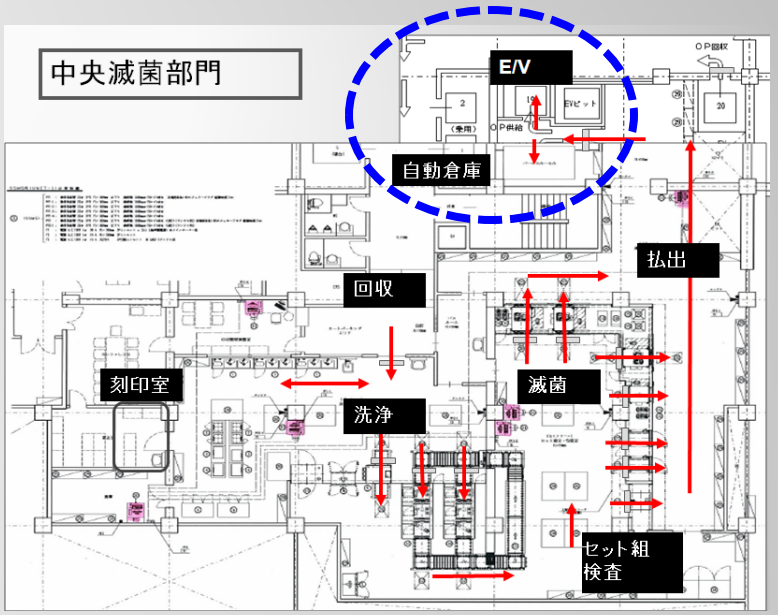


Gate-type antenna to read RFID tags for sterilization

Data entry of the start of sterilization by RFID tag

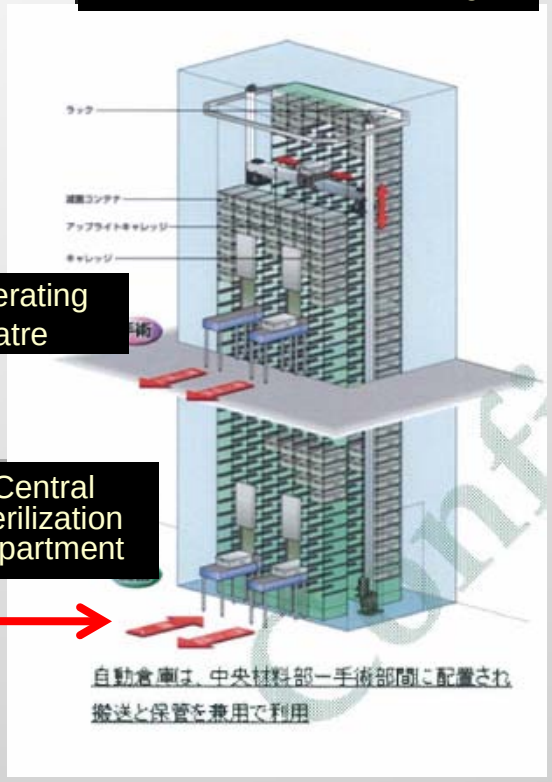
Dispatch to an operating theatre

Each time the sterilization carriages carrying the sterilization containers to which the RFID tags are attached pass through the gate-type antenna at the elevator, the antenna reads the encoded data of the RFID tags. This data is transferred as a record of dispatched containers.
Sterilization containers can be distributed or stored in the vertical automated storage system.



Vertical automated storage
for sterilization containers

Vertical automated storage



Gate-type antenna at elevator

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Conclusions

- **Efficiency of ordering operations**

Automation and laborsaving for replacement orders of damaged instruments

- **Efficiency and standardization of set assembly of instruments**

Reading two-dimensional bar codes by a single instrument enables deletion on the menu screen of set instruments.
It also enables even nonprofessional staff with insufficient knowledge of surgical instruments to identify and count instruments of a set assembly.

- **Quality Control**

Postsurgical distinction between instruments used for surgery and instruments not used for surgery enables review of instrument sets based on surgical method and simplification of the set.

- **It is possible to accurately obtain the frequency of use, the service life, the quality deterioration of an individual copper instrument set in a sterile container.**

- **When a problem occurs during surgery, the use history enables trace analysis in surgical cases.**

- **The implementation of the RFID tag system for surgical instruments has significantly improved the efficiency of automatic data tracking at each stage of instrument rotation including collection, cleaning, sterilization and dispatch of surgical instruments.**

Thank you very much for your kind attention

Seizoh Nakata

For further information, please contact

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