

Unique Device Identification of surgical instruments by DataMatrix 2D barcodes

ABSTRACT

The Robert Ballanger Hospital is a 650 bed intercity hospital. It has developed a project of Unique Device Identification (UDI) for surgical instruments and clinical services instruments. Over three years they will identify 10,000 operating theatre instruments using laser DataMatrix 2D barcodes, as well as 12,000 clinical services instruments.

The initial results, using laser technology to identify small instruments, were very promising. However, the project highlighted the necessity for regulation of the UDI. For this project EAN 128 codes were chosen, but other hospitals in France chose to use their own code. A regulation of the use of UDI would provide clarity and avoid a situation where every hospital develops its own UDI.



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Introduction

In France, as in other countries around the world, UDI of surgical instruments is not yet regulated¹. However, several French hospitals are undertaking their own UDI projects.

The Robert Ballanger Hospital is an intercity hospital. It has 650 beds: 450 medical, surgical and maternity beds and 200 psychiatry beds. 30 patient operations are undertaken in the 8 room operating theatre per day. The sterilization unit of the hospital sterilizes 120,000 products per year.

This case study presents the Robert Ballanger Hospital UDI project, and highlights two major considerations:

1. the kind of identifier and
2. the requirement of standardised UDI.

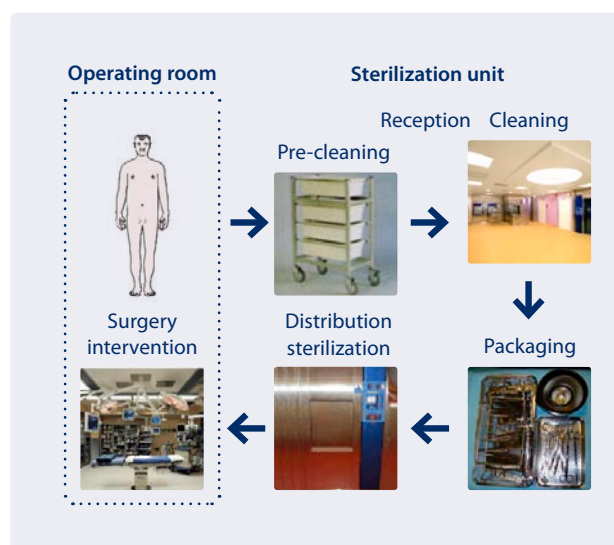
The Robert Ballanger Hospital Project

In the hospital, 9,597 sterile medical devices are in circulation. 7,381 in clinical services and 2,216 in the operating theatre, contained in 724 surgical boxes.

Since 2005, the traceability of all sterile medical devices is the responsibility of the sterilization unit, using the t-doc software (Getinge, les Ulis, France). These medical devices

can be traced from the point of return to the unit through to their distribution to clinical services. The individual steps of the process are presented in the figure 1 and for each of these steps, the agents must identify themselves.

Figure 1: Sterilization process



Up to December 2008 traceability was at the surgical box level rather than the individual instruments within them.



Consequently, if the instruments in the box changed, that change was not traceable. The decision was therefore taken to trace the individual instruments in addition to the surgical boxes.

Several important points were considered before the project:

1. What level of traceability do we want?
2. What kind of carrier will we use?
3. Which instruments will we identify?
4. What kind of code will we put on each carrier?

What level of traceability do we want?

In France, instruments are dedicated to a box. When an agent is assembling a box, the t-doc software displays its composition on a computer screen and the agent scans the instruments and must only include the associated instruments into the box.

This concept is very simple; it is easy to assemble surgical boxes and to identify the previous procedure/patient where the box was used. But there is little difference between this level of traceability and the traceability of a box.

In the Robert Ballanger hospital instruments are dedicated to a box, but it is possible to put the instrument in another box. But, as the level of identification is at the individual instrument level, traceability can be done on the box, for each instrument or for each box that included a particular instrument.

What kind of carrier will we use?

The two major kinds of carrier are Radio Frequency Identification (RFID) tags and DataMatrix 2D barcodes (figure 2).

Figure 2: Different tags



RFID tags and DataMatrix 2D barcodes are the two carriers that can be used in the operating theatre and sterilization units. RFID tags on instruments could help avoid them being left inside the patient²⁻³. This system could also assist in the exchange of data between hospitals and to confirm the contents of surgical boxes.

DataMatrix 2D barcodes are represented in 2 dimensions (2D). They can be applied to instruments directly with a label or marking by micropercussion or laser.

For this project we chose the most pragmatic system of identifying the surgical instruments with a DataMatrix 2D barcodes. 3 major reasons lead to this choice:

1. the ease of laser marking existing or branded new instruments; Indeed, 500 instruments were industrially marked per week.
2. the cost of this kind of marking. In fact, a single laser mark costs between 2 and 3 Euros, whilst an RFID tag costs approximately 7 Euros⁴.
3. the existence of software that enables this kind of traceability.

For clinical services instruments, cost effective keydots were chosen.

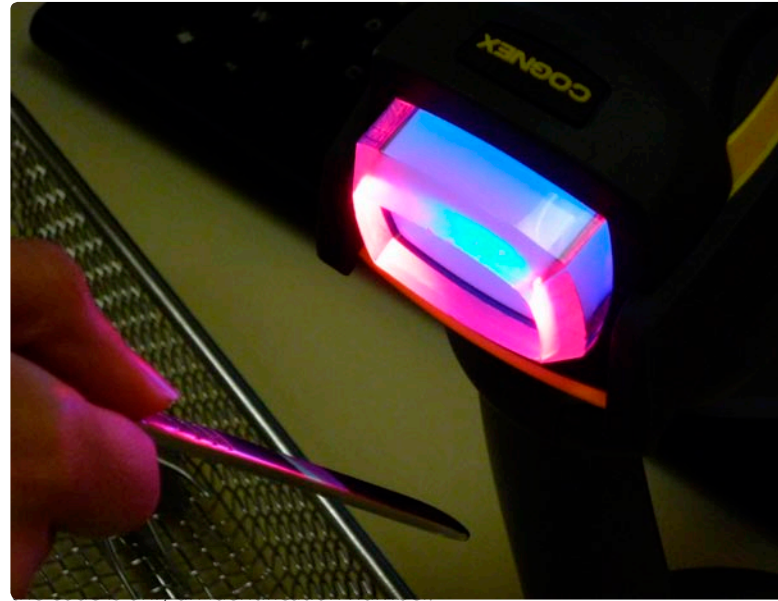
Which instruments will we identify?

The decision was to identify surgical instruments and clinical services instruments. For clinical services instruments, all the instruments would be identified with Keydots. For surgical instruments, the simple strategy was to identify the instruments with the highest usage. For example, 5 types of surgical boxes represent 12% of usage. Identifying 10,000 surgical instruments equated to 80% of usage.

What kind of code we will put on each carrier?

Due to the importance of instrument traceability, the Food and Drug Administration, the European Union or the Japanese authorities are leading reflections in this context¹. Based on these international reflections, it was determined that UDI must be based on international standards, like the GS1 System of Standards, rather than local codes specific to each hospital.

Most French hospitals are developing their own code using micropercussion DataMatrix 2D barcodes. But using a proprietary code puts the identification responsibility solely on the hospital.



In conclusion, we think that French hospitals are in advance on the UDI, but we also think that they must integrate two important aspects of UDI:

1. the international reflections on UDI to adopt an international standard like GS1, and not a local code
2. the type of UDI - the DataMatrix 2D barcode is actually the most pragmatic system.

REFERENCES

1. Medical devices and AIDC, UDI, traceability, efficiencies, global standards: Fact, future or fantasy? Eucomed, Medtech Forum, Bruxelles, 2008.
2. RFID tags help alert surgeons to problems. Healthcare Benchmarks Qual Improv 2006; 13: 118-20.
3. Rogers A, Jones E, Oleynikov D. Radio frequency identification (RFID) applied to surgical sponges. Surg Endosc 2007; 21:1235-7.
4. Landanger B. Snitem Info 2008; 175: 5.

AUTHORS

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