SURGICAL INSTRUMENT TRACEABILITY IN STERILIZATION : LEGAL OBLIGATION vs NECESSITY?

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World Federation for Hospital Sterilisation Sciences

Context

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CARE-NAM

A brand-new sterilization platform established respectively at 1, 6 and 35 km from 3 hospitals it serves around the city of Namur in Belgium (CHU UCL NAMUR (2 sites) & Clinique Saint-Luc Bouge (1 site)).

Scheduled for fall 2024

Challenge :

- Place of surgical instruments or RMD (Reusable Medical Devices) and the obligation or necessity to trace them
- Pitfalls to avoid when engaging in this approach

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- 40.000 Instruments
- 4000 SKU
- 30.000 surgeries/an

WHO - World Health Organization

2nd Global Health Challenge 2009 - WHO Surgical Safety Checklist

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist and surgeon)	Before patient leaves operating room (with nurse, anaesthetist and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? ☐ Yes	☐ **Confirm all team members have introduced themselves by name and role.**	**Nurse Verbally Confirms:** ☐ The name of the procedure
Is the site marked? ☐ Yes ☐ Not applicable	☐ **Confirm the patient's name, procedure, and where the incision will be made.**	☐ Completion of instrument, sponge and needle counts
Is the anaesthesia machine and medication check complete? ☐ Yes	**Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ Not applicable	☐ Specimen labelling (read specimen labels aloud, *including patient name*)
Is the pulse oximeter on the patient and functioning? ☐ Yes	**Anticipated Critical Events** To Surgeon: ☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss?	☐ Whether there are any equipment problems to be addressed
Does the patient have a: Known allergy? ☐ No ☐ Yes Difficult airway or aspiration risk? ☐ No ☐ Yes, and equipment/assistance available Risk of >500ml blood loss (7ml/kg in children)? ☐ No ☐ Yes, and two IVs/central access and fluids planned	To Anaesthetist: ☐ Are there any patient-specific concerns? To Nursing Team: ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns? **Is essential imaging displayed?** ☐ Yes ☐ Not applicable	**To Surgeon, Anaesthetist and Nurse:** ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

legislation in EU

Regulation (EU - European Union) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Traceability obligation concerns Class III devices

Art 27, § 9 :

- Member States encourage healthcare facilities and professionals to record and retain, preferably by electronic means, the UDI (Unique Device Identifier) provided to them.
- No requirement to register, only advice, to be implemented by May 26, 2025

legislation in EU

Regulation (EU - European Union) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Traceability obligation concerns Class III devices
Most of surgical instrument reusable concerns Class I, IIa & IIb

Aperçu de la date butoir par classe de risque

	Deadline du 26 mai	Si réutilisable (*) 26 mai
DM classe III et implants	2021	2023
DM classe II a&b	2023	2025
DM classe I	2025	2027

legislation in other countries outside EU

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Olivier Willième

Former VP EORNA
Former member of the International Relations Committee of the AORN

The question: Are there any laws or regulations on the traceability of surgical instruments in your countries ?

Answers : It seemed that there were no binding texts on the subject, in any case to trace each instrument individually and specifically

Global or local traceability at a glance

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René Magritte – La Trahison des images - Los Angeles County Museum of Art - Musée royal d'Art moderne à Bruxelles-

Reasons and benefits of individual instrument tracability

- In legal terms (traceability): Provide proof that a DM has been sterilized by the right person, at the right time, with the right equipment, under the right conditions,
- Safety (Decision support): Find, at any time, a non-conforming PRODUCT in order to remove it from the circuit.
- Economically (Production management): To have access to data which will enable you to evaluate the "sterilization" activity, its cost, its weight in terms of time spent, materials, consumables and use of other resources.

All this is already well established in the operating models of CSSD when the follow-up unit is a set, or even an individual instrument.

Reasons and benefits of individual instrument tracability

When we decide to follow each instrument individually, the reasons are more specific:

- Securing the re-composition of surgical and medical sets
- Inventory management.
- Availability of characteristics of each instrument.
- Instrument tracking throughout the process
- In the event of a post-operative complication, possibility to trace all the steps involved in handling the equipment.

In other words, safer patient care and optimized asset management.

Monitor indicators as part of instrument traceability for :

- Added-value services compared with a service provider. Our platform serves 3 hospitals, each of which owns its own instruments and sets.
- Present an activity report that accurately reflects the quality of the services provided, but also enables precise invoicing of the services provided for each of the 3 hospitals.
- Optimization of staff allocation according to activity peaks
- Modification of opening hours, with or without staff reinforcement
- Surgical instrument maintenance monitoring

Monitor indicators as part of instrument traceability for :

- Number of times units washed and sterilized
- Number of instruments per set
- Number of units and instruments recomposed by sterilization staff
- Overall instrument handling time from pre-disinfection to distribution.
- Distribution of re-composition workload by period of time.

A finer, more realistic view of the work performed

In Belgium CARE-NAM follows the recommendations of SHC

In Belgium, CARE-NAM follows the Good practices in the management of reusable medical devices of the Superior Health Council (SHC 9682 – 02/2023)

- Traceability in a CSS contributes to the good management of the MD and to the legal protection of the institution.
- Traceability is understood as the implementation of a system for tracking the MD at all stages of its life cycle and the proactive introduction of the desired processes.
- It is an essential part of a quality system. It is recommended that each healthcare institution implement such a system by referring to the ISO 13485 standard. The traceability of MDs is computerised.

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- This unique MD identification code can currently be done by datamatrix or RFID (Radio Frequency Identification).
- There are other, more sophisticated systems, such as RFID or AI, but they are not yet fully operational.
- Containers are mainly tracked, but not contents, while instruments migrate from one set to another (between 5% * to 14% **). Subterfuges are used to track individuals.

* : Chambery Hospital (France)
** : Metropole Savoie Hospital (France)

Various techniques for tracing a surgical instrument

Visual reading of a reference on the instrument				
Optical reading of a code on the instrument	Barcode	Affixed by user		
	Datamatrix	Printed during manufacturing process	by supplier	By electrochemical engraving By laser engraver
		Added after purchase	By distributor	By laser engraver By percussion engraver By fusing a Structobon By keydot bonding
			By user	
RFID recognition				
Automatic recognition: shape, weight, color				
AI recognition				

Various techniques for tracing a surgical instrument

<u>Visual reading</u> of a reference on the instrument

- Oldest technique for completing a set & identifying each correct instrument.
- The surgeon and the OR nurse have defined the instruments making up the sets and expect the CSSD staff to ensure the accuracy of the composition when it is used in surgery.
- Success of surgery depends in part on the accuracy of set composition.

+	-
• Rapid composition when the set is simple and the instruments correctly identified on the composition lists.	• No traceability to the instrument, • Risk of composition errors when two instruments look alike or do not allow absolute identification

Various techniques for tracing a surgical instrument

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Optical reading of a barcode on the instrument

- This technique, used in some CSSD, involves affixing a barcode label, created by the user and sized according to the size of the available space, to the instruments making up a set. The instruments are then read by a barcode scanner when the set is put together for sterilization.

+	-
• Rapid composition when the set is simple, and the instruments correctly read by the scanner.	• Type of information not original • Requires a considerable amount of work to identify instruments and apply a plastic label printed. • Barcode gradually fade after repeated use in LD. • Label will degrade rapidly, blistering and leaving traces of glue on the instrument. • The risk of infection is high. • Excluded from the recommendations of the SHC.

Various techniques for tracing a surgical instrument

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Optical reading of a <u>Datamatrix</u> on the instrument printed during manufacturing process by <u>electrochemical engraving</u>

- A supplier, or even a distributor, can perform acid etching. Using an acid-base etching kit with a stencil and an electrolytic liquid solution, whereby an instrument etcher passes a low-voltage electric current through gaps in the stencil. The imprint on the stencil is transferred to the instrument.

+	-
• Instrument originally marked by the manufacturer • Letters, numbers or shapes can be placed on stainless steel instruments • Unalterable, does not deform the material, does not create "stress", does not weaken or repel the material	• Difficult to realize for our old instrumentations (in-situ) • Pay attention, batch number and not always UDI

Various techniques for tracing a surgical instrument

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Optical reading of a <u>Datamatrix</u> on the instrument printed during manufacturing process by <u>laser</u>

- This technique has been used for several years by some instrument manufacturers, but not all, and is generally GS1 compliant.
  - By using an appropriate scanner to read the CSSD when the sets are reassembled,
  - By entering the data into traceability software adapted to this type of tracking,
- It is possible to trace each instrument correctly, while respecting the original composition.
- This technique is applied in the factory, and the manufacturer is responsible for the uniqueness of the coding and the quality of the printing and fusion of the metal surface.

Various techniques for tracing a surgical instrument

Optical reading of a <u>Datamatrix</u> on the instrument printed during manufacturing process by <u>laser</u>

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• Instrument originally marked by the manufacturer
• Letters, numbers or shapes can be placed on stainless steel instruments
• Technique provides
  • high-precision tracing and miniaturization of symbols.
  • a high contrast of codes and symbols (better reading)
  • a circular or cylindrical surface marking is possible.
	• External service provider or specialized technician,
	• Specific location for marking (machine volume and safety constraints),
	• specific location for anti-corrosion treatment,
	• Pay attention, batch number and not always UDI,

https://fr.gravotech.be

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on the user-engraved instrument using a micropercussion machine

Micro-percussion marking is carried out by an automatic machine and consists of applying a succession of dots to the surface of an instrument: it is based on the principle of pressing the material in.
Using an electromagnetic striker, the machine's tungsten carbide tip inscribes a Data Matrix barcode on the instrument, as well as alphanumeric characters. alphanumeric characters

www.machines-3d.com/graveuse-roland-metaza-mpx95

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on the user-engraved instrument using a micropercussion machine

+	-
• A micro-percussion machine would cost between €10,000 and €25,000. • Budget affordable for a hospital • Letters and numbers can be placed on stainless steel instruments • Able to engrave silver, copper, platinum, brass, aluminium, iron, stainless steel, acrylic, etc. • Can be used by any properly trained CSSD staff. • Easy to install. • No safety measures comparable to a laser engraver	• Impacts the metal surface • Requires a computer equipped with software dedicated to registration management, a driver for encoding, a reading system and a system for checking the quality of the marking. • Engraving requires numerous tests and adjustments, sometimes several passes of the machine. • Difficult to read small Datamatrix codes • Long-term need to re-engrave fading Datamatrix codes. • Not suitable for certain instruments, particularly cylindrical or deformed ones.

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Optical reading of a Datamatrix code on the user-engraved instrument using a <u>laser</u>

- Laser marking is based on the use of a light beam, which heats the material to 2500°C in a targeted zone, causing the surface of the material to melt.

- Laser marking quality depends on several parameters:
  - the laser's characteristics,
  - the parameters set by the operators,
  - the properties of the surface to be marked.

In the case of stainless steel, quality depends in particular on the alloy and brightness of the steel to be marked. There are many parameters to master in order to obtain a clean, visible marking without causing corrosion on the surface.

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on the user-engraved instrument using a <u>laser</u>

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• Laser engravers produce permanent, high-contrast marks on medical devices, ensuring that datamatrix are visible and legible. • Ensures operational precision and does not come into direct contact with surgical instruments, so there's no mechanical alteration or vibration to weaken metals. • Marking is robust and can withstand harsh environments and conditions. • Few or no consumables, • Versatile on countless materials - metals, plastics, silicone - depending on the settings specified.	• More expensive and require a risk analysis before purchase (Cost of professional machine is high > 45,000 €) • Different models and features need to be analyzed before purchase, often requiring the advice of experts we are not. • Requires specific training (for use, for safety measures) • Engraving cannot be improvised. Entrusted to a team member with a specific profile and serious training. • Training covers the use of the machine, where to engrave the datamatrix, what size to give it, which machine programs to use according to the materials, and requires numerous tests before "production".

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on an instrument fitted with Structobond®

- Structobond® is a label pre-printed with a Data Matrix. A strip of epoxy resin glue coats the label, which is then perfectly fixed. It is glued to the pre-sanded surface of the instrument, then baked in an oven at 180°C for 30 minutes.

+	-
• Controlled and certified biocompatibility labels • Compatible with most surgical instrument finishes • Highly resistant to detergents, mechanical stress and wear and tear • Ideal alternative to laser marking or engraving • Can be organized by color	• Labels pre-manufactured and stored in a freezer at minus 18°C. • Purchase of labels, freezer, sandblaster (+ sand), oven • Instrument must rest for 72 hours after heating • Limited to certain flat surfaces, e.g. cupules, wide instruments, etc.

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on an instrument fitted with a Keydot® by the user.

KeyDot® is a small, laser-engraved 2D Data Matrix barcode label that can be applied directly to the surface of an instrument.
It holds well on instruments made of stainless steel or thermoset polymer (medical-grade plastic).
Requires a certain dexterity and a strict procedure to apply it, placing the Keydot on the DM with fine tweezers and securing it to the instrument with the ball side of an ad-hoc paddle.

www.keysurgical.com

Various techniques for tracing a surgical instrument

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Optical reading of a Datamatrix code on an instrument fitted with a Keydot® by the user.

+	-
• Can be set up by any professional skilled in surgical instrumentation • Can be fitted in-house (no need to send to a service provider, and no equipment immobilization). • No damage to the instrument, and easy to identify on the instrument itself • The choice guided by the type of DM to be identified, its material and shape. For example, an ear speculum, even if made of metal, cannot be engraved because of its round shape. A Keydot can be applied to it.	• Code alteration due to fragmentation, detachment or deformation of the pad • Requires flat surfaces large enough for pad diameter • Possible code degradation • Requires dexterity and strict procedure for application • Must be left to rest for 72 hours before a full sterilization procedure. • Glued and could, by definition, come unstuck. • Not recommended by the SHC in Belgium.

Various techniques for tracing a surgical instrument

Automatic recognition of instrument by RFID

The RFID (Radio Frequency Identification) chips welded onto instruments instruments use a radio-frequency identification system.
RFID registration is a technology that enables data to be collected without physical or optical contact. The chip's memory capacity is 128 bits, i.e. at least 256 alphanumeric characters.
There are two possible solutions:

- either the chip is soldered onto the element, which may interfere with the operating gesture or the articulation of the instrument,
- or it is encapsulated in the thickness of the stainless steel when the instrument is created.

www.hy-smart.com/fr/rfid-product/rfid-for-surgical-instrument/

Various techniques for tracing a surgical instrument

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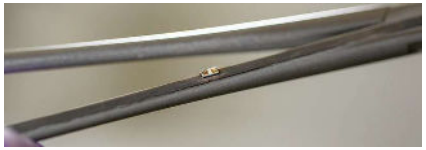
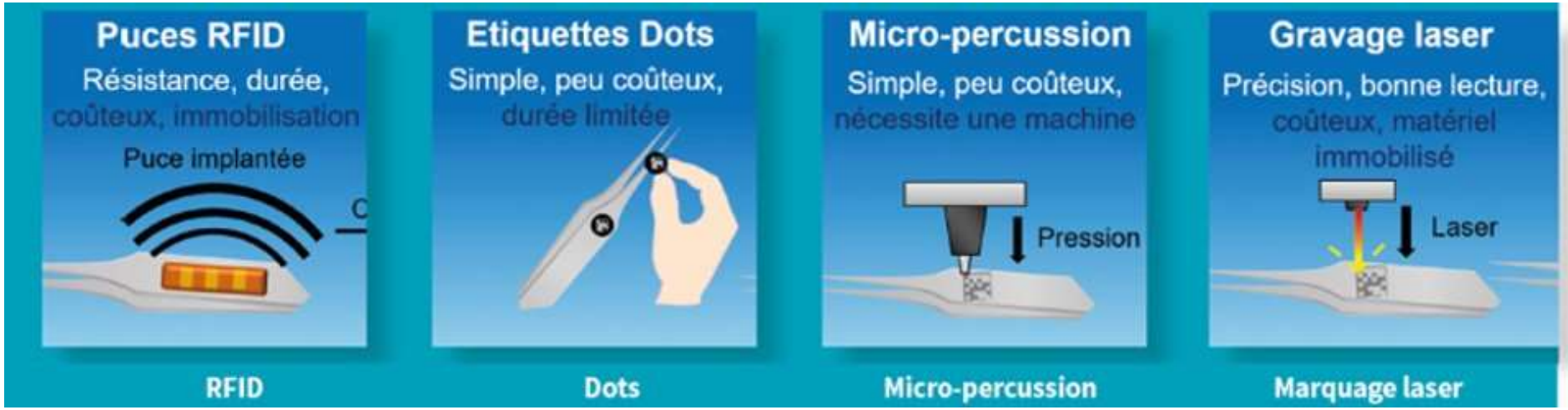
Automatic recognition of instrument by RFID

+	-
• Reading speed: a complete basket of instruments can be scanned simultaneously by the reader, • Storage capacity: greater number of characters • Possibility to modify the contents of the chip. • Reliable link to the instrument, as RFID chips are soldered or encapsulated, • Data collection at the packaging stage, but also at the end of surgery or during sterilization cleaning under unfavorable conditions (presence of organic or liquid residues) vs datamatrix. • Robustness : no chemical, thermal or mechanical alteration due to the constraints of the instruments' life cycle.	• Choice between passive and active chips, • Risk of environmental interference (operating room), • reception sensitivity (metal vs metal). • Difficult to implement for existing equipment: "hollowing out" the instruments, • Chip location to be determined in consultation with users. • Long instrument downtime, as instruments must be processed by a service provider incorporating RFID chips, • High cost compared with laser or micropercussion engraving of data matrix codes.



A prototype Smart Tool with an RFID chip and antenna attached to it, allowing for automated surgical tool tracking and counting. Credit: Wyss Institute at Harvard

Various techniques for tracing a surgical instrument



Various techniques for tracing a surgical instrument

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Automatic recognition of instrument by algorithm : shape, weight, color

These solutions can be applied to surgical instruments, particularly for ready-to-use sets where trays are designed to organize instruments in unambiguous supports. These devices measure object presence, weight, shape or color.

- Help operators reassembling surgical trays to identify and track surgical instruments, with or without DataMatrix codes, and validate their location on the tray.
- The system's algorithm identifies all types of reusable surgical devices and ensures their traceability (with or without DataMatrix code), based on their basic physical characteristics.

www.athmedical.com/ancitrak-loan-sets-traceability

Various techniques for tracing a surgical instrument

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Automatic recognition of instrument by algorithm : shape, weight, color

+	-
• Creating a full picturized database of loan sets and surgical trays • Facilitating communication between hospitals and vendors • Support during assembly processes • Sharing and creating reports, reservation and order forms, and maintenance data. • Linking specific instruments to a tray or a kit • Providing smooth integration to a hospital's existing IT system • an easy-to-use, reliable tool for safe re-composition of ancillary equipment by operators. • Highlights the difficulty of validating the precise composition of ancillaries	• Supports a portion of surgical instruments, in certain configurations • High price for use limited mainly to loaner sets, but profitable for large CSSDs • Regular encoding of new sets and instruments required • Recomposition "at the tray" could be an aid when returning ancillary equipment on temporary deposit with the supplier. • Further development and qualification of the tool is required (interfaces) • It is not really traceability by instrument.

Various techniques for tracing a surgical instrument

AI (Artificial Intelligence) recognition in CSSD

- Computer vision systems
- image segmentation,
- object detection,
- pattern recognition,
- machine learning,
- neural networks,
- depth sensors or infrared camera.

Various techniques for tracing a surgical instrument

AI (Artificial Intelligence) recognition in CSSD – "ChatGPT"

Potential future uses of artificial intelligence in the field of surgical instrument sterilization. AI could be used to

- automate and improve sterilization processes,
- helping to detect contaminants or defects on instruments,
- optimizing sterilization cycles according to instrument types,
- providing recommendations for the care and maintenance of sterilization equipment,
- track and trace instruments throughout their lifecycle.

Implementation of these technologies will require rigorous validation and compliance with current regulations to guarantee the safety and efficiency of sterilization processes.

Conclusion

Individual traceability of instruments is generally implemented to :

- prevent the risk of contamination;
- reinforce the ability to identify and recall instruments for material vigilance purposes or maintenance (communication);
- as a tool for managing technical resources;
- to monitor the quality of practices;
- reduce the risk of errors and instrument mix-ups;
- Accelerate the training for the news hires.

Today, it is note yet an obligation!

Conclusion

Not possible today to choose a single marking technology : great diversity of instruments in terms of size, shape and material,

We take care to not compromise instrument safety and performance.

We hope that this brief overview of the various instrument identification techniques will help you to make your choice of tools and approaches in line with legislation and recommendations, as well as your economic, technological and human resources.

Conclusion

CARE-NAM : our specific situation

- For us, it's obvious that instrument traceability is very important to make our process consistent! Even before the launch of CARE-NAM!
- Whenever possible, we read the supplier's datamatrix.
- For all other existing instruments in the 3 hospitals, we have opted for in-house laser engraving, and we have acquired a laser engraver to engrave our old instruments.
- We also use outsourcing (local supplier).
- We start with the traceability of unique and individual instruments...
- Engraving is only part of the project - reading is also IMPORTANT!

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CHU UCL NAMUR

Clinique Saint-Luc Bouge

Thank a lot to

Belinda

David

Olivier

Benoit

Thank you for your attention

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What's the difference between a Data Matrix and a QR code?

Code type	Data Matrix code	QR code
Maximum capacity	Numeric : 3116 Alphanumeric : 2335 Byte : 1556	Numeric : 7089 Alphanumeric : 4296 Byte : 2953
Dimension	10 x 10 → 144 x 144 cells	21 x 21 → 177 x 177 cells
Error correction	Reed-Solomon algorithm 25-33% error correction capability	Reed-Solomon algorithm Error correction for QR codes can be adjusted
Application	Supply chain traceability, direct marking for electronic components Anti-counterfeiting via serialization The only GS1-approved 2D codes for regulated healthcare products.	Additional product information - Instructions for use and recipes - Social network communication - Automatic links for spare parts orders and warranty registration - Promotions, contests and games

https://www.domino-printing.com/fr-fr/blog/2021/quelle-est-la-difference-entre-un-code-dm-et-un-qr-code

What's the difference between Barcode / Data Matrix / QR code?

Code type	Barcode	Data Matrix code	QR code
Maximum capacity	Between 8 and 13 caracters It stores less information than QR codes	Numeric : 3116 Alphanumeric : 2335 Byte : 1556	Numeric : 7089 Alphanumeric : 4296 Byte : 2953
Dimension	more than 100 bytes	10 x 10 → 144 x 144 cells	21 x 21 → 177 x 177 cells
Error correction	Not possible to assess the quality of a linear barcode	Reed-Solomon algorithm 25-33% error correction capability	Reed-Solomon algorithm Error correction for QR codes adjusted
Application	A standard barcode may be able to tell a product number and its expected location, but that would be it. Inventory management Library book	Supply chain traceability, direct marking for electronic components Anti-counterfeiting via serialization The only GS1-approved 2D codes for regulated healthcare products.	Additional product information - Instructions for use and recipes - Social network communication - Automatic links for spare parts orders and warranty registration - Promotions, contests and games

https://www.domino-printing.com/fr-fr/blog/2021/quelle-est-la-difference-entre-un-code-dm-et-un-qr-code