WHITE BOOK 2017 In partnership with Uni-HA & CHRU of Lille







Medical Devices (MD) traceability must ensure:

- Financial Monitoring
- Patient Safety
- Logistic Optimization

Regulation requires all medical devices to be labeled with a Unique Device Identifier (UDI) to allow tracking with automatic identification and data capture technology, within the healthcare supply chain from supplier to the patient, to increase patient safety and help patient care.

Indeed, most surgical trays supplied by industrials to hospitals are not engraveable and optimizing **loan and consignmen**¹ **management** is a real issue. Traceability by instrument for loan sets is very complicated, with the attendant risks:

- Incomplete set in Operating Room delaying or cancelling prescribed surgery to the patient
- Dispute with the venor due to instrument losses
- It is time consuming for the medical staff in hospital

Current process of loan or consignment set management is very human resourceintensive and time-consuming. Today, loan sets are identified through contradictory inventory, depending on the supplier's documentation and its updates, sometimes incomplete or inadequate, or even non-existent.

Inventory might be lengthy especially for complex sets such as in orthopaedic surgery, traumatology, spine surgery and neurosurgery.

Additionally, manual loan management poses higher inherent risks with human errors. During re-packaging, identifying instruments and placing them in the container will take time.

To determine the potential litigation with suppliers, a comparison is needed referring to the learning of each set.

> The study

In partnership with Uni-HA² and CHRU of Lille³, an evaluation of Ancitrak[®] traceability workstation was carried out over a 6 month period, to include loan set tracking between neurosurgery OR and Central Sterile Services Department (CSSD) – STE-RINORD⁴ - in the information system.

This evaluation aims to show productivity gain brought by the tool during contradictory inventory phases, data recording and control; and also during daily repackaging process.



The objective is also to evaluate the qualitative aspects of the system, and with user satisfaction:

- evaluate sanitary safety by implementing traceability for non engraved or unknown instruments;
- secure patient management.

Last point is to measure the benefits during recomposition based on **EasyIDm vision al-gorithm** versus Data Matrix engraving and reading, by comparing potentially achievable costs and time saving.

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(*)Long-term loan = deposit or consignment: provided for the duration of the contract.

⁽²⁾**UniHA:** Cooperative system of joint purchasing for 67 public hospitals in France

⁽³⁾**University Hospital Lille:** 1 km², 3 000 beds, 103 O.R., 14 000 employees.

(•) **STERINORD CSSD:** 2600 m², 1200 operating trays/day, automation, instruments' tracking, 80 operators, quality management.





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■ ANCITRAK[®] TRACEABILITY WORKSTATION



Ancitrak $^{\circ}$ is a workstation to help operators in surgical set reconstruction to identify and track surgical instruments with or without Data Matrix and validate their location in the set. The system allows to communicate all recomposition information directly to the sterilization software.

With a patented technology - EasyIDm algorithm - Ancitrak® identifies and ensures the traceability of all types of reusable surgical devices (with or without Data Matrix), according to its basic physical characteristics. The EasyIDm algorithm recognizes the instrument whatever its positioning direction (open or closed clamp for instance), allowing enhanced flexibility for the users.

> The EasyIDm concept, a method of tracking including two phases:

The learning phase comprising:

• positioning of the instrument on the Ancitrak® support platform.

- a catch using a digital camera positioned above the platform
- and weight measurement

The Reassembly including:

- \bullet positioning of the instrument on the Ancitrak $^{\circ}$ platform
- physical recognition of the instrument, comparing with the database.

Ancitrak[®] generates recording booklets upon arrival and recomposition report identifying the content of the set after sterilization.

> Benefits of EasyIDm system

With the EasyIDm system, there is no need to mark instruments, which is relatively expensive and time-consuming. Additionally, implementing this system helps prevent infectious risks resulting from instrument tampering and corrosion issues due to engraving.

Furthermore, Ancitrak[®] ensures conformity of instruments with unreadable Data Matrix. Indeed, the codes have the disadvantage to degrade over time, due for example to the wear induced by the numerous sterilization cycles.

And last but not least, this solution avoids the obligation to CE mark the instruments. Indeed, instrument marking might imply CE-marking procedure, following directives when substantial modifications have been brought to a product.

> UDI compliance

In combination with White Reader[®] (Data Matrix reader), Ancitrak[®] complies with UDI requirements. Ancitrak[®] can deal both with Data Matrix engraved instruments through their code reading with White Reader[®], or with unmarked instruments, like instrument sets that cannot be marked. This combination can be achieved for the learning and recomposition of one single set.



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Inventories: Ancitrak® provides reassembly proofs to share responsibilities: between OR and sterilization; and between sterilization and the ancillary supplier, in case the loan physical inventory is not corresponding to the book inventory (provided by the supplier). In supplier litigations issues, a comparison is needed referring to the learning of each set. Ancitrak® provides in real time storage inventories.

Stand-alone: Ancitrak® incorporates a reassembly software adapted for independent configuration (standalone). It does not require a network connection or rely on other software.

Inter-Ancitrak[®] communication:

Ancitrak® workstations can be networked for the purpose of synchronizing databases, for an easy sharing of data between sterilization and OR, giving the opportunity to easily implement "inspection" in OR.

- Whole computer: Ancitrak® acts like a whole computer with the option:
 to connect devices like a printer for easy printout of reports, barcode reader...
- to access network and web applications (sterilization software, internal resources...)







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LEARNING PROCESS: PRODUCTIVITY SAVINGS

> The study

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590 loans (102 different types of surgery instrument sets, approximately 66375 instruments) were completed during the study. Around 75% of the instrument sets did not include implants. Instrument sets were divided into 2 categories: loans and deposits.

Instrument sets are composed of operating room grade instruments. In CHRU Lille, 1 set is estimated as follows: with an average of 25 instruments per tray, and 4.5 trays per instrument set.

COMPARISON OF MANUAL VS AUTOMATED PROCEDURE

> Manual process (see also diagram 1) As a first step, the operator responsible for traceability identifies visually each instrument from his own knowledge and/or from reference photographs. Then he enters manually the instrument reference in a computer system allowing the tracking of instruments in the hospital; and finally, he places each instrument in the trays. Alternatively, he can use an optical reader to capture Data Matrix codes marked on the instruments. With the reading, the computer system automatically identifies the instrument, whose information is automatically integrated into the system.



Diagram 1 MANUAL PROCESS IN CHRU LILLE

	Deposits	Loans	
Pharmacy	Pharmacy reception	Pharmacy reception	
OR	inventory and nomenclature	inventory and nomenclature	
staff	edition with photos	edition with photos	
CSSD	check and entry	check conformity between	
staff	in sterilization software	sheet and real composition	
CSSD	recomposition	recomposition on basis of paper	
technicians	with CSSD software	composition supplier sheets	

Contradictory inventories: For

each kit, learning is carried out only once, on new set arrival (or when implementing Ancitrak® in a hospital). In the framework of contradictory inventories, it permits computer recording of the real set's content (and not from supplier lists).

Nomenclature edition: In parallel and in a fully transparent manner for the user, Ancitrak[®] records data required for instrument recognition. A one-step procedure permits simultaneous photo shooting, identification (physical measurements recording) and data capture (supplier, reference, denominations, quantities, Data Matrix codes, positioning into the tray...). **Database** can be shared, with exchange on recorded learning data between the different Ancitrak® workstations: a model remains master of the other models.

Booklet: A composition booklet is published which might serve as contract between the hospital and the supplier on loans' arrival in the facility.



LEARNING PROCESS: PRODUCTIVITY SAVINGS

> Ancitrak automated process

STEP 1 OR staff: inventory and nomenclature edition

Step 1 with the automatic method, Ancitrak® showed 44% time-saving compared to the manual method. Both loans and deposits reached this rate, explained by the one-step procedure. Indeed, Ancitrak® permits simultaneously contradictory inventory and nomenclature edition with photos in a single stage.

In greater detail, time saved per instrument during learning process was 26 seconds.

The Nomenclature Edition A One step procedure! In simultaneous :

- Photo shooting
- Identification
- Data capture

STEP 2 By CSSD staff

• Loans: check conformity between supplier sheet and real composition Productivity gain when checking achieved 48% for loan instrument sets. In more detail, time saved per instrument during learning process represents 10 seconds.

• Deposits: check and enter in sterilization software

During specific procedure for deposits with the checking and data recording in the CSSD software, productivity gain represented **88%**. In more detail, time saved per instrument during process was 63 seconds.



Savings applied to the CHRU Lille Productivity gains were calculated for a calendar year for each category of instrument set: 590 loans and 30 deposits being processed annually. Regarding loans, productivity gain represents 553 hours saving. Whereas deposits show 83 hours saving.



Applied to CHRU Lille instrument set stock

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REASSEMBLY PROCESS: PRODUCTIVITY SAVINGS

Reassembly allows instrument recognition, their location in the tray if necessary, computer registration and validation of the right recomposition. Traceability is carried out for each re-packaging in OR and CSSD (see diagram 2).

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Reassembly is also an efficient support for instrument verification related to materiovigilance.

In software terms, Ancitrak®:

- Records reassembly (with date, agent name and exact set content when processed in sterilization)
- Saves data to a server
- Generates and publishes recomposition booklets.
- Prints recomposition booklets on shared network or local printer

Ancitrak[®] coupled with the **White Reader[®]5** device can also manage mixed recompositions, combining instruments with or without Data Matrix; or identify instrument with unreadable Data Matrix.



efficiently and all Data Matrix codes of medical equipment, whatever the type of instrument (shiny, mat, curved...) and type of marking (laser, dotpeen)



Diagram 2 Traceability steps in OR and CSSD (in CHRU Lille)





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REASSEMBLY PROCESS: TIME SAVINGS

> Impact of complexity on time saving

Ancitrak[®] proved to be time efficient, right from complexity class n°1. The positive impact on productivity is amplified when complexity class of the instrument sets is at its highest level. Class 5 reached 55% productivity gain, with 15 second time saving per instrument (diagram 3a and 3b).

Based on time consumed during manual recomposition for each instrument, the following complexity classes have been identified:

Diagram 3a IMPACT OF COMPLEXITY

Complexity class	Manual recomposition time for each instrument	Time saving per instrument	Productivity gain
0	< 5s	-2S	-79%
1	5 to 10s	0,2S	3%
2	10 to 15s	2S	17%
3	15 to 20s	5s	26%
4	20 to 25s	9s	41%
5	> 25s	15s	55%

Diagram 3b PRODUCTIVITY SAVING







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[°] **REASSEMBLY PROCESS**

> Instrument examples per class complexity

Class	Instrument set name	Pictures of trays
5	EASYSPINE LDR Medical Orthopedics Nb instr: 39 Trays: 3	
4	CLYDESDALE Medtronic Orthopedics Nb instr: 11 Trays: 2	
3	NEX-LINK ANCILLAIRE Zimmer Trauma Nb instr: 36 Trays: 2	
2	AVENUE-L 2/2 LDR Medical Trauma Nb instr: 28 Trays/ 2	

The more complex the kit, the more time you save!



REASSEMBLY PROCESS

> Best practices for improved security

Considering that class o can be manually re-packed, then time saved is 368 hours. In view of the CHRU's organization, including recomposition in OR and CSSD, **productivity gain moves to 736 hours** (368*2).

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However, regarding complexity classes 0 and 1, for which the impact has less significance on risk management (respectively -79% and 3%), Ancitrak[®] is still recommended offering the option of manual validation. Consequently **Ancitrak[®] preserves the benefit of** security during complete recomposition. The median productivity gain would then be increased to 34%.

Furthermore, since the study, productivity efficiency has been enhanced by adding a confusion management system. This system offers multiple choices, particularly interesting for trays with instruments of various dimensions (example class 1, Zephir 3, Medtronic).

Diagram 4 PRODUCTIVITY SAVING



> Productivity gains applied to CHRU Lille

In CHRU Lille, **18486 trays** are processed yearly and were classified into different complexity classes (see diagram 5).

Considering CHRU's organization (recomposition in OR and CSSD) the total annual productivity saving represents more than **700 hours**.

Ancitrak[®] is a more attractive recomposition help than the paper process version, particularly for **short-term loans** for which composition is little-known or unknown. Additionally for complex trays with multiple layers and/or including numerous instruments, positioning instruments into the tray with Ancitrak® is facilitated thanks to an identification system using colored dots: blue to indicate the position of current instrument to be placed by the user, green for the already processed instruments and red for the missing ones (photo 1).

Diagram 5 COMPLEXITY CLASSES IN CHRU LILLE



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REASSEMBLY PROCESS

Photo 1 RECOMPOSITION SCREEN





ANCITRAK®: ENHANCED SECURITY AND REAL TIMESAVER

During the study a users' satisfaction survey was led to analyze the ergonomics and the ease of use of the workstation. The study was performed on a representative sample of 16 CSSD staff, and the questionnaire was submitted **after the first use of Ancitrak**[®].

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F Testimonial

"Ancitrak® sounds to be a very interesting and useful tool to implement in our daily sterilization practice. Notably, by improving surgical instruments traceability, innovative technologies are needed to really enhance patient's safety."

Christine Denis, President of WFHSS, STERINORD, France

92% of users in CSSD and OR felt satisfied by the system in terms of ergonomics and usability.



PRODUCTIVITY GAIN VS INSTRUMENT DATA MATRIX MARKING PROCESS IN LILLE

> Time saving without Data Matrix

Managing loan sets is depending on a tripartite system (CSSD, OR, supplier) which is complex to manage. Instruments cannot be marked as they are not the property of the hospital. Additionally, losses of loan sets or their mismatch can be charged by the suppliers.

Lille hospitals took the initial step of marking instrument sets, but this turned out to be expensive and unproductive. Consequently, they decided to stop the marking, releasing suppliers from liability (Zimmer).

Instrument marking with Data Matrix needs following steps:

• Code engraving

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- Code reading with a Data Matrix reader
- Code assignment in the sterilization software

On average, the marking process in CHRU Lille is estimated around 5 minutes (300 seconds) per instrument.

On basis of previous assumptions, namely:

- 25 instruments/tray
- 4.5 trays/instrument set

TIME SAVING (HOURS)



> Financial gain on the marking

The potential financial economy was calculated for 590 non-engraved loan instruments in Neurosurgery and Orthopedics ORs.





CONCLUSION AND EVOLUTION SINCE THE STUDY

> Productivity saving in learning process

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Compared to conventional manual process, Ancitrak[®] greatly improved inventory and indexation of loan sets in O.R. reducing time by 44%.

In CSSD, time spent for **conformity composition was reduced by 48%** for short-term sets and **88%** for new permanent sets.

Ancitrak® showed significant time advantage for long-term loan sets. This is explained by:

• the absence of manual data input into the traceability-dedicated software. Ancitrak® communicates automatically all information to the sterilization software, avoiding manual data input, and consequently avoiding human errors.

• the one step procedure during the nomenclature edition. Ancitrak[®] permits simultaneously contradictory inventory and nomenclature edition with photo captures in a single stage.

> Exponential growth in productivity depending on complexity

Ancitrak[®] provides great help for short-term loan sets and complex operating trays, with improved traceability and assembly safety. Re-packaging time and storage was improved especially for short-term loan sets whose composition is poorly known by operators, and for complex trays including numerous instruments or multiple layers.

Additionally, positioning instruments into the tray with Ancitrak[®] is facilitated thanks to its identification system.

Compliance rate showed on average, 9 out of 10 recognitions. This correlates with the operating tray complexity, showing reduction when the set is made of implants or very similar devices.

> Users' satisfaction

92% users in CSSD and O.R. were satisfied regarding ergonomics and usability. And 90% of them felt enhanced security for the recomposition step.

Ancitrak® is a very interesting and useful tool to implement in daily sterilization practice.

Notably, by improving surgical instruments traceability, innovative technologies are needed to really enhance patient's safety.





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