Traceability and scalability

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OnSolution

PO Box 1007
Baulkham Hills 2153

Phone (+61 2) 9614 6417
Fax (+61 2) 9614 6891

e-mail sales@onsolution.com.au

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1 About this manual

This manual covers:

- An introduction to LTrace and should be read by all new operators
- Features and benefits of LTrace. This provides an overview of the features and is not essential for all users to read. At least one person should take the time to read this section to get the full benefits from their installation.
- Operator instructions for all screens are provided typically as a reference section.
- The setup guide provides information on setting up a new system and should be consulted before configuring the system.

Introduction and overview

2 Introduction

The LTrace software and process was developed to meet the Quality Assurance requirements of

- Sterile Service Departments both large and small,
- General Practictioners,
- Dentists

where the tracking of sterilised item from the moment of sterilisation to the moment of use is essential. The information and procedures it brings will assist in ensuring that the requirements for accreditation are easily met.

About this manual

The LTrace user manual contains the following sections:

- Introduction and overview: This covers the concepts behind LTrace and is intended to explain what is being achieved. It is not essential for all users to read this section but CSSD and theatre managers should look through it.
- Daily Usage Guide: This provides reference material on specific sections of LTrace. It can be used either as a reference guide or read through systematically to get maximum benefit from LTrace.
- Configuration Guide: This provides information on how to setup and customise LTrace. CSSD and theatre managers should read it to ensure that they have correctly configured the system and are getting maximum benefit.

3 Traceability

In a manual system

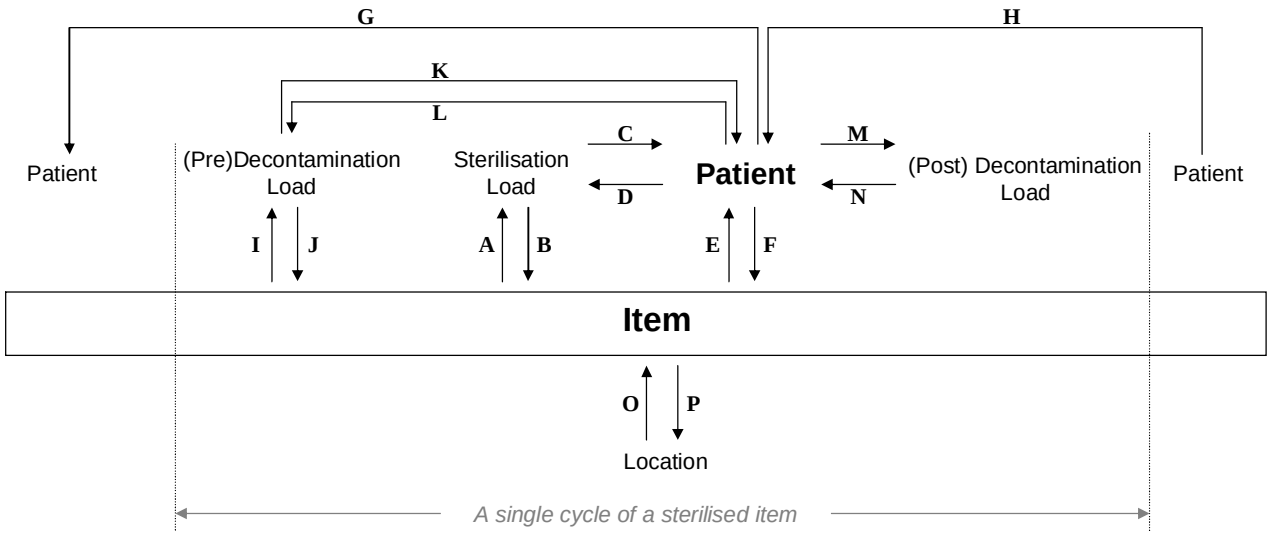
There are various levels of traceability. The minimum standard currently required is to be able to trace a sterilized item back to the sterilization batch. This is typically achieved by placing a sticker on the sterilized item indicating the batch.

This, however, does not automatically provide the opposite – that is, it does not automatically provide traceability from the batch to the item. The only way that all items that were sterilized in a batch can be determined is by manually checking every item to see when it was batched. This is further complicated by when an item is used on a patient.

Once the item has been used, the sticker is moved to the patient's notes. Now it is possible to tell that the patient had an item used on them that was sterilized from a particular batch but there is no way of telling what that item is.

Full scope of traceability

Item to batch, however, is just one minor aspect of traceability. The following diagram shows the potential scope of traceability for an item. The table then provides examples of the type of question you can answer if you have this information and when it is likely that you would ask such a question. There are many more questions that can be asked and answered but this will give you a good starting point to understanding the potential of LTrace.



Type	From	To	Typical questions	Reasons
A	Item	Sterilisation	When was this item sterilised? How often has this item been sterilised?	Use-by Usage count

			In which batch was this item last sterilised? *(This last question is the only question a manual tracking system can answer quickly)*	
B	Sterilisation	Item	Which items were sterilised in this load?	Recalls Financial Utilisation
C	Sterilisation	Patient	Which patients used items from this load?	Spread
D	Patient	Sterilisation	This patient used items from which loads? Is there a common load for these patients?	Source
E	Item	Patient	Which patients used this item?	Spread
F	Patient	Item	Which items were used by this patient?	Source Financial
G	Patient	Patient	Which patients used this item before this patient? (Technically this is F + E i.e. patient to item followed by item to patients where the item is uniquely identifiable)	Source
H	Patient	Patient	Which patients used this item after this patient? (Technically this is F + E i.e. patient to item followed by item to patients where the item is uniquely identifiable)	Spread
I	Item	Decon	When was this item last washed?	Use-by
J	Decon	Item	Which items were washed in this load?	Recalls
K	Decon	Patient	Which patients used items from this load?	Spread
L	Patient	Decon	This patient used items from which loads? Is there a common load for these patients?	Source
M	Patient	Postdecon	In which loads did this patient have items washed in?	
N	Postdecon	Patient	This load contained items from which	

			patients?	
O	Location	Item	What items are at this location?	Stock take
P	Item	Location	Where is this item?	Locating

Then there are questions that are answered by combinations of the above such as:

- Where are the items that were sterilized in this load? (BP: Sterilisation to item to location)
- Who else used items sterilized in the same loads as those items used on this patient? (FABE: Patient to item to sterilization to item to patient)

And there are many other questions that can be answered. Once the information is in a central location it can be quickly retrieved. Management questions become simpler as well:

- How many loads happened each day?
- How many items are processed during each hour of the day?
- What is the average number of items per load?
- How many items are rejected?
- How many items get returned unused?
- What items are in short supply?

CJD

CJD tracking requires the ability to track an item from patient to patient. To achieve this the item must be uniquely identified within L-Trace. This allows tracking from the patient to the specific item back to the patient (E + F) and is shown as G and H in the diagram.

Pre and post decontamination

A manual label system focuses only on the sterilisation batch to the patient. LTrace extends this to the decontamination batch prior to sterilisation (pre-decontamination) through to the decontamination batch after its usage (post-decontamination).

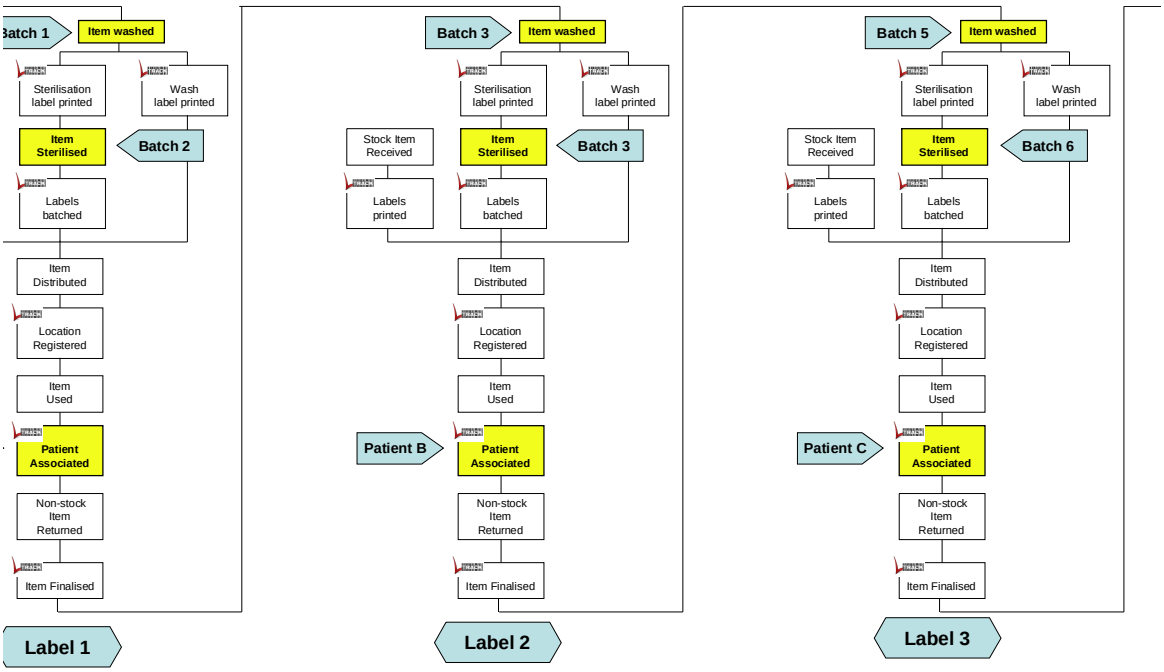
Pre-batching is when the item has been decontaminated *before its usage*.

Batching is when the item has been sterilised *before its usage*.

Post-batching is when the item has been decontaminated *after its usage*.

Where this concept becomes more complex is when the focus is placed on a decontamination batch. In this case it is useful consider what happens to various types of items.

Unique items



A unique item will be traceable onto its next usage. In this case the item's previous label will be linked to the next label. The decontamination batch is the post-batch for the first label and the pre-batch for the next label. There are two labels linked to the one batch – the one that went in dirty and the one that came out clean.

Label	Pre-batch	Batch	Post-batch
1	1	2	3
2	3	4	5
3	5	6	

When the focus moves onto a batch it is possible to see from the above table that both labels 1 and 2 were in batch 3, and both labels 2 and 3 were in batch 5.

A simple way of considering this is that label 1 went into batch 3 and label 2 came out of batch 3. (It doesn't matter that the label was actually created/printed later, the concept is correct).

Non-unique items

A non-unique item that is scanned back into a decontamination load will terminate at the load.

Decontamination only items that were decontaminated in the load will have their pre-batch set only. It is possible for them to be later scanned back in and to have a post-decontamination batch set as well.

Does it matter?

The source of an infection is being investigated. The first step of the investigation is to go back to the decontamination load that the item was washed in. In this step the focus is to look at the pre-decontamination load.

By looking at all other labels with the same pre-decontamination load it is possible to try and find other patients that may have become infected, or items that need to be recalled.

By looking at labels with this batch as their post-decontamination load will assist in finding the source of the infection.

How is this achieved?

To get to this level of traceability it is necessary to scan labels back into CSSD into the decontamination load that they were cleaned in.

This is easily achieved where the item has its own bar code on it or where the labels have been removed from the wrapping and returned with the goods (on a "patient sheet" for example). LTrace also displays a list of items that were recently used.

This level of traceability is beyond the current requirements of the standards but is strongly recommended, especially once items are uniquely identified.

Other questions

This chapter focused on item level tracking. At the same time there is a large amount of extra information that can be gathered. This includes:

- Equipment loads
- Equipment services
- Biotests
- Loansets
- Fast track
- Additional items to be invoiced
- Locations

This then opens the system to answering questions such as:

"How many loads have we done with each steriliser this month?"

"How many breakdowns have we had?"

"How reliable is the equipment?"

"Which items are continually being fast tracked?"

"Which department uses the most of this item?"

"Where are these items?"

Once you have the information within LTrace then you can get answers to these type of questions fast. There is no more guess work, or hours of wading through paperwork.

So next time you recommend that more sets are required you can back it up with a complete list of how often it has been fast tracked over the past 6 months.

4 Sterility assurance

Validation and Assurance

In order to provide assurance that items are sterile, the SSD must monitor every stage of the process.

Validation is an essential part sterility assurance. Validation is basically being able to prove beyond doubt that the equipment works and that the department can repeatedly produce sterile products by using a proven system which includes quality control measures.

The LTrace software is designed to assist in the recording of results as well as, where possible, ensuring that a process is followed. It is critical to remember that **LTrace can not provide assurance on its own**. It relies on staff having good procedures and that they follow them.

In particular, there are no substitutes for visual inspection and common sense. The LTrace system should not distract staff from inspecting items nor using common sense to handle emergencies and exceptions to the rule.

Software or procedures

The LTrace software and the procedures should be tightly integrated. While many features in LTrace are optional, ignoring them may produce assurance gaps. For example, counting items in and out of the usage area is optional. Experience, however, has shown that all theatres should take a very active role in ensuring that all items are accounted for at the end of the surgery.

At the same time LTrace does provide flexibility to adapt to current procedures or work flow. For example, when recording which items were sterilised in a batch it is possible to:

- Record them as the labels are printed,
- Record them before the sterilisation process using a scanner,
- Record them after the sterilisation process using a scanner,
- Record them using the computer.

Each option has its own set of advantages and is a matter of personal choice.

LTrace + Procedures = Assurance

When introducing a tracking system, review your procedures to ensure that you are achieving the best outcomes possible for your facility based on your budget, staffing levels and equipment. LTrace can be customised to suit your work environment but at the same time “that’s the way we have always done it” is not necessarily a good reason to keep on doing it that way.

The benefit of a database

All labels are recorded in the database. Other information includes

- who printed the label,
- who inspected the batch,
- who accepted the batch,
- who rejected items,
- where the item was used,
- which patient used the item

Along with

- what maintenance occurred on the equipment,
- what routine tests are required

All of this information means that it is possible to report afterwards on a wide range of issues. These include:

- which other patients used items from a sterilisation batch as another patient,
- how many times a particular piece of equipment was used,
- how many items went through a particular piece of equipment

5 Scalability

To understand how L-Trace is scalable the following should be kept in mind:

The number of items added to the database

- "Unique" and "non-unique" items provide the ability to simply enter a type of instrument or tray or a specific instrument/tray. For example you may have 5 identical trays in circulation. By marking them as non-unique they only have to be entered into L-Trace once and the operator selects that tray. You have the benefit of minimal setup but you can trace the tray's usage from the person packing it, to the sterilization load to the patient that uses it. What you can't trace is which patient used it before and which patient used it afterwards. To do this the item must be unique within the system. All 5 trays must be individually entered into the system and uniquely marked/identifiable. This takes time.
- Specifically, it takes your time. So you decide how many items are "high risk" that must be individually tracked. As they come through the first time you enter them into L-Trace and optionally print a barcode to place on the item. There is no reason why you can't start with all non-unique items and progressively make them unique.

The amount of information available

- L-Trace is able to display:
  - A pick list
  - With unique serial numbers if the item is unique
  - A photo of the item
  - Photos of each component
  - Detailed instructions on what to do
  - Storage instructions
- Most of this takes your time to configure. So you can start with those items that are often incorrectly processed and expand to all items over time.

The options for finding items while packing

- Step 2 above requires the staff to identify the item that they are packing. Unique items ideally have a barcode on them. By using a barcode reader you will immediately identify that item. It takes 5 seconds and has a 0% error rate. We strongly recommend the use of barcode readers. A Bluetooth (no wires) barcode reader costs more than a cabled barcode reader but keeps the workbench clear of mess. A cabled barcode reader, however, is only a couple hundred dollars.
- Step 2, however, can also be achieved by using a name matching feature or a simple structure to find items. You don't need a barcode reader.

Item tracking

- As the items move from CSSD to theatre/wards it is possible to track exactly where they are. This requires PCs and scanners to be available. In reality,

however, you know that it is somewhere between CSSD (since the load was accepted) and the patient (since it hasn't been scanned to the patient). This is the best place to save money initially.

Decontamination

- It is possible to scan returned items back to the decontamination load. This is not required by the standards. It is definitely advisable but not mandatory.
- It is also possible to print labels for decontaminated only and stock (not decontaminated or sterilized) items. Once again, this is not required by the standards but is possible.

Scalable, not modular

L-Trace has all the functionality built into every installation. This means that a single PC version of L-Trace could do everything.

In reality, however, most facilities will want some functionality within CSSD (e.g. printing labels) and other functionality in theatre. To achieve this, you just need to buy the hardware (PC, possibly a scanner or printer) and a license for another PC.

The following section on traceability builds upon the concept of adding more functionality in by typically adding more equipment. The key point is that you have ALL of this functionality already at your disposal; you just need to start using it.