

Title: Genealogy for LC Equipment

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1. PURPOSE

The purpose of this procedure is to define the requirements for establishing product genealogy.

2. SCOPE

This procedure applies to the genealogy of Liquid Chromatography (LC) Instruments as produced by Milford Instrument Operations and the Contract Manufacturers.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
ASP	Work instruction document type in SAP and serves as a Waters Assembly Procedure
DHR	Device History Record, a compilation of records containing the production history of a finished device.
Genealogy Record	A history of any required instrument/subassembly/component lot/serial numbers related to an upper level instrument serial number
N/A	Not Applicable
PCBA	Printed Circuit Board Assembly
SAP	Enterprise Resource Planning (ERP) system used at Waters
Traceability	The ability to follow the history, application or location of items, material or activity by means of records.

4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Operations Management	- It is the responsibility of management to ensure implementation of this procedure and affiliated Standard Operation Procedures (SOP). - Review and/or approve all necessary documentation deliverables.
Manufacturing Engineer	- Identify components and/or assemblies to be tracked and recorded. - Write, review and/or approve all necessary documentation deliverables. - Work with various engineering functions towards problem resolution.
Assembly Operator	Record appropriate components and/or assemblies prior to customer shipment.

5. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730000523	Good Documentation Practices (GDP) Procedure
WAT000050MP	Waters' Record Retention Corporate Policy
730000483	Global WI/Operating Procedure Template
735002132	Genealogy Data Entry, SigmaSure
730002669	SigmaSure Genealogy Work Instruction
730000709	Device History Record Procedure
730003005	Work Instruction for Instrument Traceability

6. FORMS

Doc No:	Document Title
730002048	Manual Genealogy Template

7. HEALTH & SAFETY

No Health & Safety specific considerations.

7.1. Equipment/Materials of Use

Personal Computers or other input devices may be used.

8. PROCEDURE**8.1. General Requirements**

Genealogy is an application that enables the traceability of materials/components/assemblies lot/serial numbers for Waters' Instrument Operations Liquid Chromatography (LC) products. The traceability will enable Waters Corporation to support the appropriate actions in the event the product needs to be located (refer to procedure 730003005).

8.1.1. Any system (manual or electronic) may be used to capture this information. Electronic system for capturing the data is preferred, but in the cases where it is not feasible or the electronic system is not functioning, it is acceptable to use a manual method of recording the data. Template 730002048 or equivalent may be used to record the data manually. The following minimum requirement must be met:

8.1.1.1. The genealogy record shall include:

- Part number and serial number of the top level product.
- Part numbers and lot/serial number of materials/components/assemblies which were chosen to be tracked within the products.

8.1.1.2. A hard copy of the record must be signed, dated and filed in the DHR as per procedure 730000709.

8.1.1.3. All component/sub-assemblies to be recorded must be uniquely labeled or identified through serialization or lot/batch number.

8.2. Genealogy Guideline

Roles	Tasks/Instructions
Manufacturing Engineer	8.2.1. Consult with the appropriate stake holders and select instrument and materials/components/assemblies to be tracked based on but not limited to the following considerations: • Items that require internal (Waters) test records • Materials/components/assemblies of key supplier(s) • Field replaceable unit(s) • Items that require complex or new manufacturing technologies • Major components/sub-assemblies (Example: PCBA, Power Supply) 8.2.2. Document the select instrument and materials/components/assemblies in an electronic genealogy system or ASP.
Assembly Operator	8.2.3. Record or Scan the following per the appropriate electronic genealogy system or ASP. • Part number and serial number of the top level product. • Part numbers and lot/serial number of materials/components/assemblies which were chosen to be tracked within the products. 8.2.4. Sign, date and filed a genealogy record in the DHR prior to shipment as per procedure 730000709.

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