

Title: New Test Equipment Development Procedure

Document No: 730001834

Version No: 03

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1. PURPOSE

Δ This procedure defines the inputs and deliverables required to design, document and release equipment produced by Test Engineering. This procedure applies to test equipment for instruments, sub-assemblies/spares, Printed Circuit Boards (PCB), and any equipment referenced by a TE number. Also, it defines information/documentation control for design record(s) and software.

2. SCOPE

Δ The scope of this procedure is all equipment purchased, designed and/or constructed by the Waters Test Engineering Department in Milford MA.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
TE	Test Equipment or Test Engineering
Test Equipment	Equipment, that is typically comprised of hardware and software, and is required to perform a non-destructive test that demonstrates the product meets applicable specifications.
TEDD	Test Equipment Design Documentation: Records that detail the design of Test Equipment, this may include but not limited to Test Equipment Design Plan, Computer Aided Design (CAD) files, software, software source code, drawings, schematics, bills of material, design notes, or other means used by the Test Engineer to document the design.
OESR	Operations Engineering Service Request
N/A	Not Applicable
SAP	Systeme, Anwendungen und Produkte (Systems, Applications and Products), German ERP software
Calibration	A process to ensure that equipment is capable of producing accurate results. This includes verifying measurements and/or making adjustment(s) to ensure measurement accuracy.
PM	Preventive Maintenance: The servicing, for the purpose of maintaining equipment in satisfactory working order, by performing systematic inspection, detection, and correction of potential failures. PM activities may include tests, measurements and parts replacement.
Qualification	The documents and activities that ensure specified test equipment is installed properly and functional requirements are fulfilled. This is accomplished by executing protocols developed to verify the test equipment.
UUT	Unit Under Test
PCB	Printed Circuit Board
ICT	In-Circuit board Test using various measurement techniques to ensure electronic components are properly assembled and meet designated tolerances.
FCT	Functional Circuit board Test, typically performed in the last phase of PCB production, as a final quality control. FCT is performed to ensure that the unit under test (UUT) fulfills its functional specifications. FCT consists of simulating the operational environment to check functionality, including: communication, driving loads, generating and reading signals necessary to make the UUT work properly.
Supplier	Any facility which provides component, subassembly or instruments, including component and subassembly vendors as well as contract manufacturing facilities.
Production Support Checks (PSC)	Tests performed in support of product design specifications to assure product quality, and/or verify pre/post test conditions.

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Test Specification and Procedure	A document that provides the test specifications and step-by-step instructions to execute production testing.
TSP	Test Specification and Procedure / Test Procedure document type in SAP
CAL	Calibration or Preventative Maintenance Procedure document type in SAP
CAD	Computer Aided Design
DIR	Document Information Record

4. ROLES AND RESPONSIBILITIES

Role	Responsibilities
Test Engineering Manager	- It is the responsibility of management to ensure implementation of this procedure and affiliated Standard Operation Procedures. - Assign Test Engineering staff to approved projects. - Review and/or approve documentation deliverables.
Test Engineering	- Develop product test solutions. - Develop and qualify test equipment required to implement production testing at Waters or its suppliers. - Write, review and/or approve all necessary documentation deliverables. - Provide test equipment support / usage training. - Work with various engineering functions towards equipment development.
TE Technician	- Support Test Engineers in test equipment support activities. - Write and/or review documentation deliverables. - Support, service and maintain test equipment. - Work with various engineering functions towards equipment development.
R&D Engineering	- Provide Product Specifications - Provide development Test processes where appropriate - Work with various engineering functions towards problem resolution.
Development Team	- This team may include but not limited to New Product Introduction (NPI), Manufacturing Engineering (ME), Reliability Engineering (REL), Research and Development Engineering (RDE) and Test Engineering (TE). - Δ Develop/document production test requirements. - Work with various engineering functions towards problem resolution. - Review and/or approve all necessary documentation deliverables.

5. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730001833	Test Engineering Management Policy
730001836	Sustaining Test Equipment Procedure
730001835	Test Equipment Qualification Procedure
730001799	Calibration and Maintenance of Measurement and Test Equipment
730001292	Release and Revision of Non-Catalog Tool
730000483	Global WI/Operating Procedure Template
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy

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Δ 730000837	Waters Global Validation Policy
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6. FORMS AND TEMPLATES

Doc No:	Document Title
730001945	Test Equipment Design Plan Template
N/A	TEDD Templates
730001946	Test Equipment Design Review Checklist
730001947	Test Equipment Release Form
730002013	Test Specification and Procedure (TSP) Template
730002014	Calibration and/or Preventive Maintenance Procedure Template

Note: Forms and templates that do not have a document number will be maintained in the 'TE' folder on the 'finserv2' server.

7. RECORDS

All deliverables will be stored and maintained in SAP, but in the cases where the test equipment predates this procedure, the records may be stored in a physical folder, which resides in Test Engineering or electronically in the 'TE' folder on the 'finserv2' server.

- In addition to the required links shown in the table below. The TSP will be linked to the UUT part number in SAP.
- Test equipment software / firmware source code will be maintained in the 'TE' folder on the 'finserv2' server. Test equipment software version will be maintained in the TSP and visible on the test equipment.
- Documents captured in SAP will have a class code (the first 3 digits), a 6 digit core number and a 2 letter suffix. (Ex. TE0084000EQ) The Test Equipment documents stored in SAP are structured as follows:

DIR and Description	Stored Deliverables	Required Link(s)
TE0#####EQ Test Engineering Equipment: This is the main Test equipment file and contains all documentation pertaining to the design.	Test Equipment Plan (Traceability Matrix) Design Review Checklist TEDD (Excluding Mechanical CAD files)	UUT TSP Cal / PM Procedure
TE0#####ME Test Engineering Mechanical: This contains CAD drawings for fixtures enclosures etc. A 999##### DIR may be substituted or referenced.	Mechanical CAD File(s)	TE0#####EQ
Δ TE0#####QA Test Engineering Validation documentation (protocols)	Δ Equipment Design Verification Protocol (EDV) Operational Qualification Protocol (OQ) as required Performance Qualification Protocol (PQ) as required	TE0#####EQ
Δ TE0#####QX Test Engineering Validation documentation (design): This contains all qualification / validation reports, with executed protocol scripts attached as objective evidence, for the design of the system.	Equipment Design Verification Report (EDVR) Test Method Validation Report (TMVR) Validation Assessment Form (VAF) – (for design or multiple system changes)	TE0#####EQ
Δ TE0#####01 ... TE0#####99 (Suffix based on individual system #) Test Engineering Validation documentation (system): This contains all qualification / validation reports, with executed protocol scripts attached as objective evidence, for individual systems.	Δ Submission Form Installation Qualification Report (IQR) Operational Qualification Report (OQR) as required Performance Qualification Report (PQR) as required Submission Form Validation Assessment Form (VAF) – (for single system changes)	TE0#####EQ
TE0#####SF Test Engineering Software: This will contain a document indicating the test software revision and location of any necessary software.	Test Equipment Software or a document referencing the locations stored.	TE0#####EQ

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Note: All listed deliverables may not be required. Please refer to the appropriate procedure to clarify the deliverables required.

8. HEALTH & SAFETY

No Health & safety-specific considerations.

8.1. Equipment/Materials of use required

Not Applicable.

9. PROCEDURE

9.1. New Test Equipment Development Procedure (Refer to flowchart in section 10)

Roles	Tasks/Instructions
Requestor	9.1.1. For new products, the development team will work with Test Engineering to identify and request the need for a test solution, which typically requires test equipment to be created or revised. 9.1.2. For released products, an OESR form will be submitted to request the need for a test solution, which typically requires test equipment to be created or revised (ref. 735001836 Sustaining Test Equipment Procedure).
TE Manager	9.1.3. The Test Engineering Manager will assign test equipment design to a specific Test Engineer or Technician based upon the skill level and knowledge required for the task and in consideration of group work load. 9.1.4. Based upon work load and project time requirements, the Test Engineering Manager may elect to contract a supplier for external design of any project or part of a project. If all or a portion of the Test Equipment design is contracted to a supplier, the assigned Test Engineer is responsible for all coordination of the supplier's design, documentation, qualification and delivery of the equipment.
Development Team	9.1.5. Test Engineering will develop a Test Equipment Design Plan (ref. 730001945) in conjunction with the New Product Development Team. This plan details: • Design internally or outsource • Estimated cost of the test equipment • Estimated time frame • An initial traceability matrix, which will reference all applicable design documentation and include PSCs for the product and/or its major sub-assemblies that must be tested and/or measured. 9.1.6. The development team must review and approve the Test Equipment Design Plan. Test Engineering will revise as necessary.
Test Engineer	9.1.7. The Test Engineer will design the Test Equipment or contract the design to a supplier. This may include developing "proof of concept" software and hardware for

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	the design. 9.1.8. In developing the test equipment, many factors are to be considered; these may include all or a subset of the following: • Test equipment for similar standard products • Instrument production volume • Test equipment location • Consideration will be given to development of a suitable guard band between product design specifications (design tolerance limits) and limits of acceptability for production tests.
Test Engineer Manufacturing Engineer	9.1.9. Δ For test equipment designed internally, a design review will be administrated. At minimum, a representative from Test Engineering (other than the Test Engineer that designed the equipment) and a representative from Manufacturing Engineering (with the exception of PCBA test equipment) are required for a review (Others may be invited if applicable). A test equipment design check list will be reviewed and capture any issues or requests. 9.1.10. The assigned Test Engineer will address all issue(s) and request(s) captured in the design review. The assigned Test Engineer will implement any action(s) required and review with the team from the design review.
Test Engineering	9.1.11. For test equipment designed internally, Test Engineering will procure and receive parts, components and materials. 9.1.12. For test equipment designed internally, Test Engineering will configure and build production test equipment. 9.1.13. For test equipment designed externally, Test Engineering will specify, order, and receive the equipment. 9.1.14. For all test equipment, Test Engineering will evaluate and debug any issues. 9.1.15. For all test equipment, Test Engineering will develop all appropriate TEDD(s). 9.1.16. For all test equipment, Test Engineering will develop and release a Test Specification and Procedure (ref. 730002013), Calibration and/or Preventive Maintenance Procedure (ref. 730002014). 9.1.17. Execute qualification per procedure 730001835. If the test equipment fails the qualification go to section 9.1.14. If the test equipment passes the qualification proceed to the next step. 9.1.18. Conduct initial training of test equipment to the appropriate personnel. Note: ICT & FCT fixtures may not require training of personnel. 9.1.19. Fill out the release form (ref. 730001947) and submit for approval to release test equipment. Once complete release in SAP.

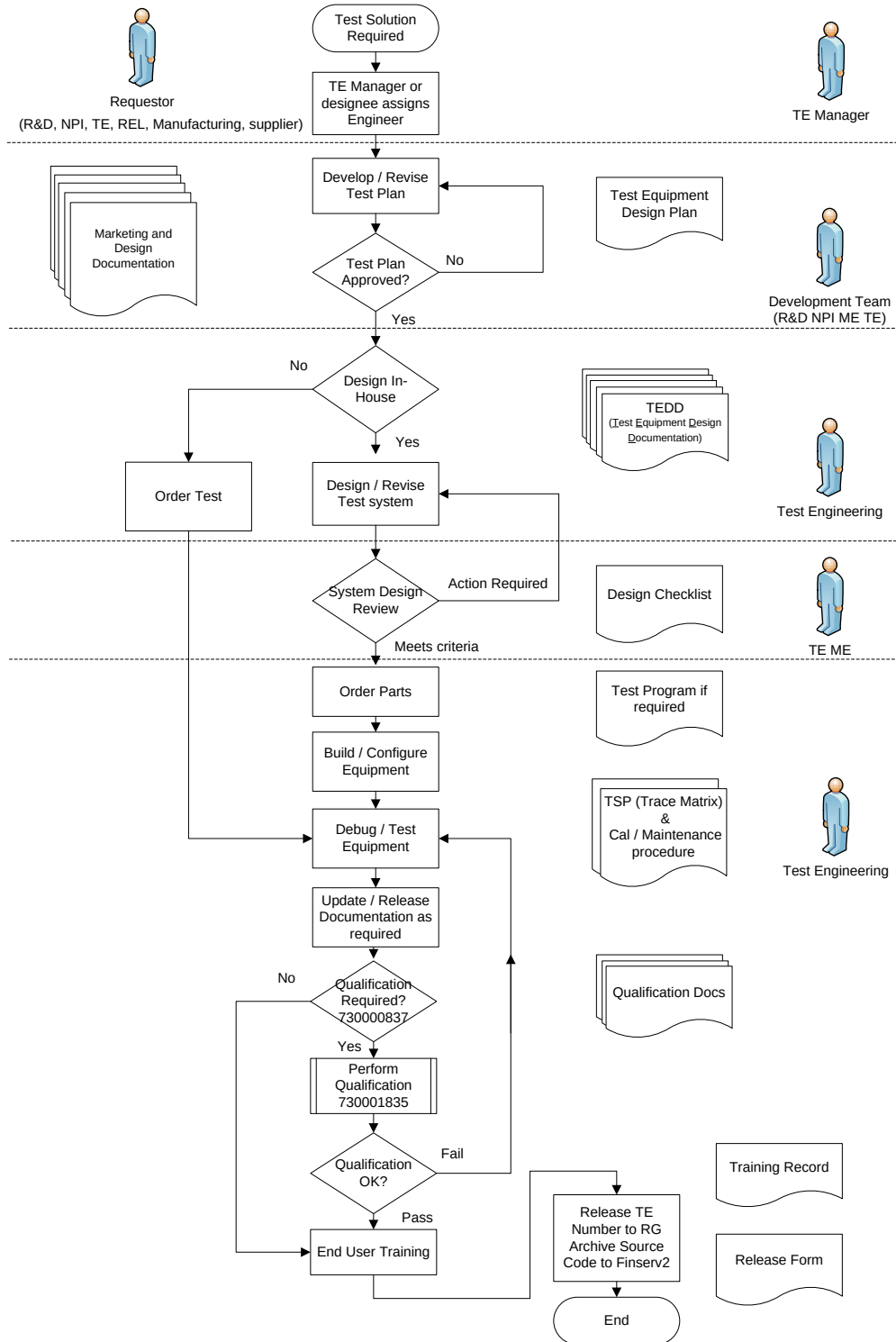
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10. Δ NEW TEST EQUIPMENT DEVELOPMENT FLOWCHART



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DOCUMENT HISTORY

VERSION:	03	ORIGINATOR:	Ed Jackson	Change ID:	N/A
SUMMARY OF CHANGE: All changes have been mark with the delta symbol. Revise Document 730001834 to V03 including the following changes: • Revised section 1 Purpose to include supporting equipment. • Revised section 2 Scope to include all equipment purchased. • Revised section 5 to include 730000837. • Revised section 7 Table to reference IQR, OQR, PQR, EDVR, VAF, TMVR and EDV. Remove the word process. Added row for TE0#####01 – TE0#####99 information. • Revised section 9.1.9 to include the exception of PCBA test equipment. • Added “Qualification Required?” decision diamond in section 10 Flowchart.					