

Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Protocol No: Multiple_WPPL_TE-02OCT17-VAF	SAP No: TE008XXXXQX (depending on the TE number)

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change (please refer to Attachment 01) to the following released test equipment:

	Description	Equipment ID	Location in Venture, WPPL
1	PCM II Tester	TE82817-2	Waters Production Floor
2	TCM II Tester	TE82818-2	
3	PCBA board Tester	TE82824	
4	Column Manager Functional Tester	TE82987-1	
5	Aquity Column Manager Tester	TE82984-1	
6	Aquity CMA/CMA AUX Tester	TE83026-1	
7	Aquity CMA/CMA AUX Tester	TE83026-2	
8	2475, ALTUS A-10 FLR, ACQUITY UHPLC OPTICS ALIGN	TE83031-1	Clean room
9	FLR OPTICS BENCH ALIGNMENT	TE83032-1	

This document shall also define the deliverable(s) required to qualify the change to legacy test equipment used in production environment for number of years.

Qualification of the equipment shall ensure that it functions within its specifications post change.

2. BACKGROUND

Test equipment listed above is custom designed test systems used to verify functionality of various Waters LC instruments. All of the listed test systems have been utilized in production environment for number of years and have been releasing Waters final instruments into the various applications.

Test systems located on site of Venture Corporation manufacturing - approved Contract Manufacturing of Waters LC instruments.

Venture's quality management system meets the ISO 9001:2008 requirements.

3. DESCRIPTION OF CHANGE

Due to the introduction of new process to the Venture production, minimum rearrangement of production testers are required to facilitate this change. See Attachment 01 for testers' location adjustment.

No changes are made to the tester specification, software/firmware, and hardware. Testers are placed on moving trolley and hence the equipment will be shifted as a complete system without any cable disconnection. Test equipments location will be rearranged within the same facility and within the exact same controlled environment.

It is Venture's responsibility to maintain the appropriate controlled operation requirements and appropriate personal training. The compliance objective evidence shall be monitored via annual regulatory surveillance and recertification audits per requirements of ISO 9001:2008.

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4. RISK ASSESSMENT

4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
If the change affects software, does the change affect the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
If the change is due to firmware, is the test system used to download firmware?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
If the change is mechanical, electrical, pneumatic, and/or hydraulic in nature, does the change alter the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocating to a different facility?	☒	☐

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Duplicate System or Process	No	Yes
Is the change a duplicate system, test method, or process?	☒	☐

4.2.2. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.3. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☒	☐

4.2.4. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
If the change is due to firmware, is it an instrument firmware update?	☒	☐

4.2.5. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocated within the ~~Milford~~ ^{Venture} site? 484 030672017	☐	☒

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- 4.3. An answer of Yes to any of the questions in Section 4.1 above results in a high risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.
- 4.4. An answer of Yes to any of the questions in Section 4.2 above results in a medium risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

5. HAZARD ASSESSMENT:

There are no changes being made that would potentially introduce to the environment, operator, assembler, service technician or end user.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

6.1. Complete the tables below based on the qualification or requalification recommendations:

6.1.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification Software not affected by this change.		

6.1.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☐	☒
Comments/Justification It is beneficial to verify the performance of test equipment upon move to the new location within the same site. The following shall be performed on each test equipment to demonstrate successful move of each system: 1. Execute IQ-06 test script of Installation Qualification Procedure 730004135 2. Write the IQR using 730002845 demonstrating the equipment's ability to perform as expected 3. Upon approval of IQR upload this document and copy of approved IQR to the appropriate directory of SAP for each test equipment		

6.1.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification No TMV required due to this change of legacy test equipment. Refer to the Milford Process Validation Procedure 730001835 section 9.2.2 for the risk based assessment of the change.		

6.1.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐

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Comments/Justification 100% critical to quality (CTQ) attributes verified.
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6.1.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification 100% critical to quality (CTQ) attributes verified.		

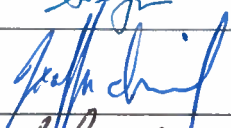
6.2. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; therefore, there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- Is there any impact to documentation, calibration or facilities/utilities? No. This change to the existing production test equipment does not impact documentation, calibration or facilities/utilities.
- Any impact on production schedules (particularly if the system requires production to be stopped)? There will be impact to the production schedule. It is responsibility of IQ protocol executor to work with the Ventures' production schedule to arrange the execution of UUT pre and post move. *Not applicable per 6.1.2. OK 03 Oct 2017*
- What resources are required for implementation (personnel, materials, machines, etc.)? Yes. WPPL Test Validation Engineer will be responsible for deliverables, identified in this assessment form.
- Will additional training be required? There is no documentation change associated with the change. All training remains valid.

8. APPROVALS

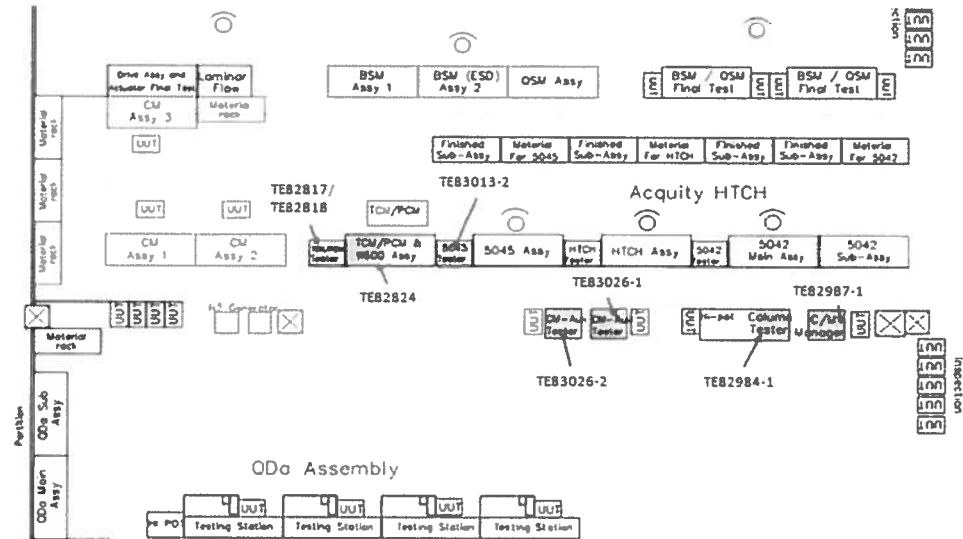
Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Author (Originator)	YAP SIEW YEE	TEST VALIDATION ENGINEER		03 OCT 2017
Reviewer (System Owner)	Jaffar Ismail	Test Engineering Manager		03 Oct 2017
Approver (Site Quality or Delegate)	Andre Kopoyan	Senior Ops. Quality Engineer		03 Oct 2017

Note: Once approved all items in the Assessment section designated "Yes" are actions to be assigned and executed. These completed items shall be scanned and saved to SAP, as defined in 730001835, Process Validation Procedure for Milford Site, and the wet copy shall be provided to Test Validation Engineering to be archived.

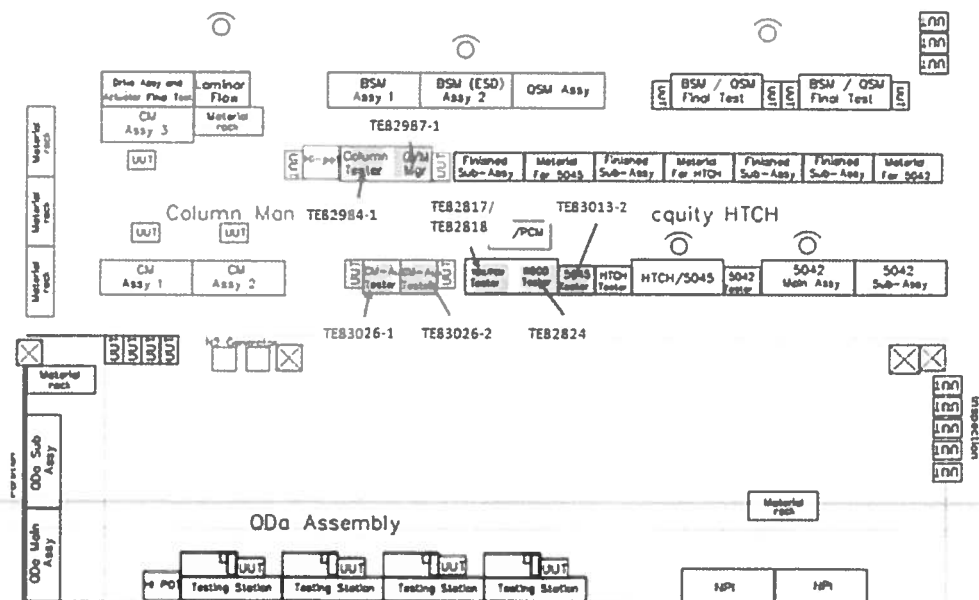
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Attachment 01

Description: Current Column Manager Testers Locations in Waters Production Line



Description: New Column Manager Testers Locations in Waters Production Line (after rearrangement)



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Attachment 01 (continue)

Description: Optic Bench Alignment Testers locations (before and after rearrangement)

