

1.0 Purpose

The purpose of this Test Equipment Qualification (TEQ) protocol is to define the procedure used to install and qualify the ACQUITY CPSM RTZ Assembly Tester (TE82995). The scripts in this TEQ protocol will guide a trained performer to successfully install the test system and verify all the components and consumables are present.

Once completed, the executed TEQ test script data sheets will be included within a Test Equipment Report (TER) which will serve as objective evidence that critical requirements of the test equipment adhere to Test Engineering's requirements and recommendations.

2.0 Background

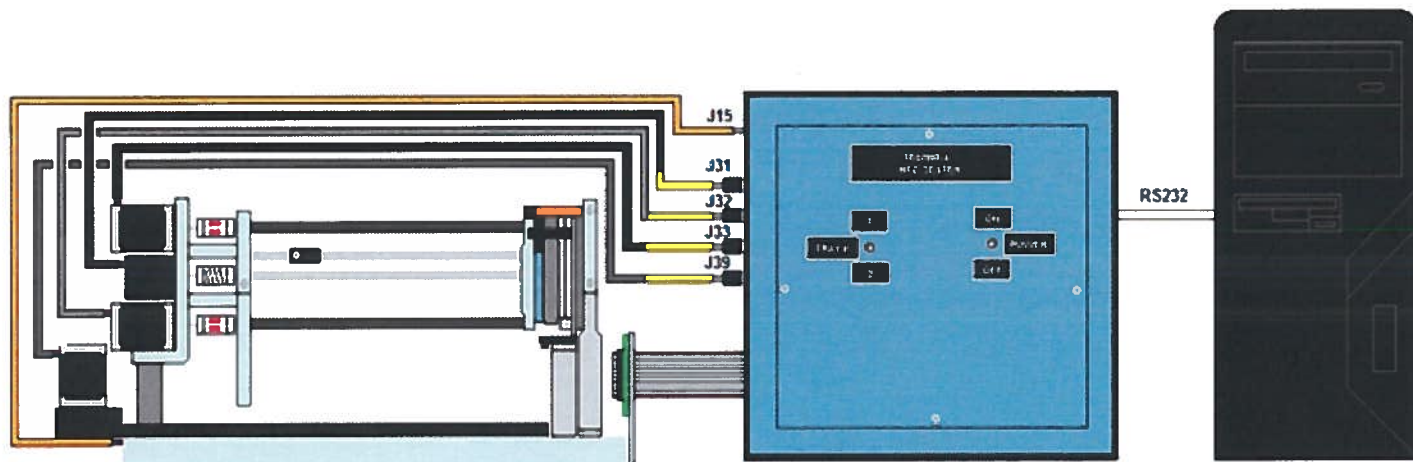
TE82995 resides in Milford and at GES Venture in Singapore. It is used to test multiple versions of the ACQUITY CPSM RTZ Mechanism which is used in all models of the H-Class, I-Class and M-Class FTN and FL Sample Managers.

TE82995 consists of a PC running a custom Labview program, power supply, CPSM Driver Board, CPSM Control board, and CPU2000 loaded with CPSM firmware. All measurement values are derived from the UUT positioning system.

The RTZ assembly consists of 3 major components, the Theta Drive assembly, the Radial Motor Stack assembly, and the Needle Carriage assembly, all of which are spared parts.

The Labview program interfaces with the CPU2000 CPSM firmware. It performs a series of calibrations, then exercises the UUT while monitoring for errors.

The components of the RTZ Assembly are not serialized so the test program generates a serial number based on a date/time string, such that the test report can be saved in the SigmaSure database.



TE82995 - INTERCONNECT DIAGRAM

3.0 Definitions and Abbreviations

Term	Definition / Abbreviation
TEQ	Test Equipment Qualification
TER	Test Equipment Report
UUT	Unit Under Test
CPSM	Common Platform Sample Manager
TSP	Test and Specification Procedure
SAP	Enterprise Resource Planning (ERP) software
FTN	Flow Through Needle

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4.0 References / Related Documents

Doc No:	Document Title
730001833	Test Engineering Management Policy
730001835	Test Equipment Qualification Procedure
730002845	Test Equipment Report Template
735000814	2420 Lamp Alignment Fixture TSP
735002817	2420 Lamp Alignment Fixture CAL/PM
735000711	2420 ELS Detector Performance Specification

5.0 Acceptance Criteria

The TEQ will be considered successful when all appropriate sections have been completed, all acceptance criteria have been met, and a TER has been written (in accordance with 730002845, Test Equipment Report Template), and has been approved.

Objective evidence will be included within, or attached to, the associated TER and referenced to the script and step numbers. Examples of objective evidence include, but are not limited to: all completed protocol test script data sheets, screenshots, calibration certificates, photos, test reports, etc. Do not leave any fields blank. If not applicable fill in N/A.

5.1 Failure to Meet Acceptance Criteria

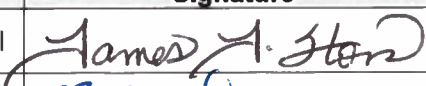
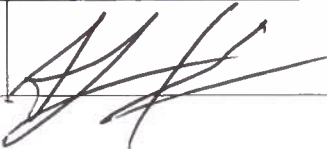
The pass/fail decision is based on the number and severity of discrepancies found during the qualification. In the event that there is failure to meet any of the acceptance criteria, the TER signatories must decide to:

Accept (with justification) or reject the qualification. In the case of a rejected qualification, Test Engineering will assess and record the risk; then make the necessary changes and re-qualify the test equipment. All test results, deviations and conclusions will be summarized in the TER.

6.0 Training

All personnel performing any part of this TEQ shall be trained to this protocol, and the TSP when applicable, prior to the start of any testing and a Training Record shall be filled out and attached to the associated TER. A blank Training Record is provided as part of this instruction.

Approval of Protocol (Prior to execution)

Responsibility	Name (Print)	Title	Signature	Date
Author	James J. Stors	Test Validation Engineer II		10 JAN 2017
Reviewer	Richard Davis	Principal Test Engineer		10 Jan 2017
Approver (Quality)	Andre Kopoyan	Senior Operations Quality Engineer		12 Jan 2017

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TEQ Test name: Associated Documentation Verification		Test Script No.: TEQ-01	
Test Equipment No. TE82995- _____		Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester	
Installation Site:			
Purpose: To verify that supporting documentation is available prior to the completion of qualification. Test execution: Complete the table below. Verify that the documents are in either the Ready or Release General state in SAP. If documents are unavailable state why in the comments section. Objective evidence: Completed Test Script Data Sheet SAP Screen shot of below available documents			
Type	Doc. No., Title, Rev. No.	Status in SAP	Initial & Date
Test and Specification Procedure	ACQUITY CPSM RTZ Assembly Tester TSP 735002271 Rev. _____		
Maintenance Procedure	ACQUITY CPSM RTZ Assembly Tester PM 735002816 Rev. _____		
Comments:			
Overall Test Conclusion: ☐ Pass ☐ Fail			

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TEQ Test name: Site Verification			Test Script No.: TEQ-02	
Test Equipment No. TE82995-_____		Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester		
Installation Site:				
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test execution: Verify and/or measure the items listed below. Record details (Name, Asset No, serial number, etc) of the meters and/or gauges used to execute this script in the comment section below. Objective evidence: Completed Test Script Data Sheet. Photo of work area. Copies of calibration certificates for gauges or meters used.				
List	Acceptance criteria	As found	Pass/Fail	Initial & Date
Ambient Temperature	Temperature is between 18°C and 28°C.			
Relative Humidity	Humidity is between 10% and 80%, non-condensing.			
Space	Sufficient room for the test station and the UUT, leaving sufficient room for UUT and test station service.			
Test station bench	Large and strong enough to support the Test Station.			
Electrical Supply	100-240 VAC, 50/60 Hz			
Electrical Outlets Available	3 or more dedicated.			
Comments:				
Overall Test Conclusion: ☐ Pass ☐ Fail				

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TEQ Test name: Instrumentation Calibration Verification			Test Script No.: TEQ-03	
Test Equipment No. TE 82995-_____		Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester		
Installation Site:				
Purpose: To list all critical instruments associated with test equipment and to verify that all critical instruments are in the calibration system and calibrated. Test execution: Verify that all critical instruments have had a preventive maintenance performed and have been included in the preventive maintenance schedule. Objective evidence: Completed Test Script Data Sheet Copies of calibration and maintenance certificates.				
Description	Waters Asset No.	Last Cal/PM Performed Date	Cal/PM Due/Expiration Date	Initial & Date
TE82995 Test Box				
Comments:				
Overall Test Conclusion: ☐ Pass ☐ Fail				

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TEQ Test name: Flywheel Weight Verification		Test Script No.: TEQ-04	
Test Equipment No. TE 82995-_____		Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester	

Installation Site:

Purpose:
To verify that the Flywheel Tool, part number 999037997, has a weight within specification.

Test execution:
Using a calibrated scale, weigh the Flywheel Tool, part number 999037997, used for testing and ensure that it meets the acceptance criteria.

Objective evidence:
Completed Test Script Data Sheet
Copy of calibration certificate for scale used.

Description	Weight (kg)	Weight (kg)	Pass/Fail	Initial & Date
Flywheel Tool, Part Number 999037997	3.35 +/-0.5			

Comments:

Overall Test Conclusion:
☐ Pass
☐ Fail

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TEQ Test name: Test Software and Instrument Firmware Version

Test Script No.: TEQ-05

Test Equipment No. TE82995-_____

Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester

Installation Site:**Purpose:**

To verify that the installed software details have been recorded.

Test execution:

Verify the Test Equipment Software version listed in the TSP and displayed on the Test Equipment are identical.
Launch HyperTerminal and enter the command "version" at the console:> prompt to receive back the FTN Firmware version.

Objective evidence:

Completed Test Script Data Sheet

List	Acceptance criteria	As found	Pass/Fail	Initial & Date
Test Equipment Software	TSP : 16 Test Equipment: 16	TSP : Test Equipment:		
FTN Firmware	Version 1.60.364 or above			

Comments:**Overall Test Conclusion:**☐ Pass☐ Fail

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TEQ Test name: General Safety Check		Test Script No.: TEQ-06	
Test Equipment No. TE82995-_____		Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester	
Installation Site:			

Purpose:

To verify that the test equipment can operate in a safe manner, within its designated location.

Test execution:

Perform an inspection of the equipment to assess its safety related condition. Note: If any of the below requirements are not met then the overall test conclusion is deemed "Fail".

Objective evidence:

Completed Test Script Data Sheet

Copy of calibration certificate for Hi Pot/Ground Tester used.

Inspection	Requirement	Pass/Fail	Initial & Date
Mechanical Safety/Pinch Points/Sharp Edges	None Found		
Electrical Safety Hi Pot/Ground Continuity	Passed per test specification WAT046538		

Comments:

Overall Test Conclusion: ☐ Pass ☐ Fail

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TEQ Test name: Performance Test Verification

Test Script No.: TEQ-07

Test Equipment No. TE82995-_____

Test Equipment Name: ACQUITY CPSM RTZ Assembly Tester

Installation Site:

Purpose:

To verify that testing the specified Units Under Test and achieving a passing result for all UUTs will demonstrate that the test system is capable and reproducible. The UUT consists of a combination of three (3) major components, the Theta Drive assembly, the Radial Motor Stack assembly, and the Needle Carriage assembly. For assemblies tested in Milford the Final Test Record in SigmaSure is filed under the RZZ Mechanism part number (279001993, 279002008, 279003321). For assemblies tested in Singapore the Final Test Record in SigmaSure is filed under the RZZ Mechanism with Datum Plate part number (279001698).

Test execution:

For test stations located in Milford, five different UUT's of any combination of RZZ Mechanism part number 279001993, 279002008 and/or 279003321 will be tested per the TSP. Any combination of Needle Carriage and Datum Base will be used for the UUT. For test stations located in Singapore, seven different UUT's of part number 279001698 will be tested per the TSP. Record the Serial Number, test software version installed/used for testing, test result and initial & date below. A result of PASS indicates that the correct software was installed and used to obtain a Final Test Record with all tests passing. Test Software Version requirement: 16

Objective evidence:

Completed Test Script Data Sheet

Copy of the Final Test record for each UUT

UUT Sample Number	Serial Number	Test Software Installed	Pass/Fail	Initial & Date
Sample #1		Version: _____		
Sample #2		Version: _____		
Sample #3		Version: _____		
Sample #4		Version: _____		
Sample #5		Version: _____		
Sample #6		Version: _____		
Sample #7		Version: _____		

Comments:

UUT Part Number: 279001993 **Weekly Lot Size:** Average 34 per week October-December 2016 - Milford
UUT Part Number: 279002008 **Weekly Lot Size:** Average 8 per week October -December 2016 - Milford
UUT Part Number: 279003321 **Quarterly Production:** 7 total between October -December 2016 - Milford
UUT Part Number: 279001698 **Weekly Lot Size:** Average 85 per week October -December 2016 - Singapore
Sample Size: 5, for Milford, **Sample Size:** 7, for Singapore
(Part number 279001993, 2792008 and 279003321 are functionally equivalent)

Overall Test Conclusion:

☐ Pass

☐ Fail

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TRAINING RECORD

Document No. _____ **Procedure Title** _____ **Version** _____

Training by: _____
Printed name Signature Date

By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

Printed Name	Signature	Initials	Date

Copy this Training Record Template as needed