

For the 2489 ACQUITY TUV Pre-test Download Station

PREPARED BY

Name	Role	Signature	Date
James J. Stors	Senior Test Validation Engineer	<i>James J. Stors</i>	10 AUG 2020

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer	SEE ATTACHED E-MAIL	

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed.

APPROVED BY

Name	Role	Signature	Date
Ashley Deschenes	Principal Operations Quality Engineer	SEE ATTACHED E-MAIL	

The "Approved By" signature denotes that this system change risk assessment and resulting planned process validation activities has been approved.

James Stors

From: Eric Turner
Sent: Tuesday, August 11, 2020 2:00 PM
To: James Stors
Subject: RE: TUV System VAF's

Hi Jim, thanks.

This email will serve as my digital signature in accordance with TMD010801

Eric Turner
Principal Test Engineer

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34 Maple Street
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From: James Stors <James_Stors@waters.com>
Sent: Tuesday, August 11, 2020 1:52 PM
To: Eric Turner <Eric_Turner@waters.com>
Subject: TUV System VAF's

Hi Eric,

Think we're all set. I got a good argument from Mark as to why we don't need to perform an EDV for the new TE82903 program (it's identical to the others – except the part numbers) and a good summary of the TE82964 system.

Please review and provide back.

Regards,
Jim

James Stors

From: Ashley Deschenes
Sent: Wednesday, August 12, 2020 3:33 PM
To: James Stors
Subject: RE: VAF's for TE82760, TE82882, TE82903, TE82964, TE82969, and TE83057 Systems

Hi Jim,

I approve all VAFs detailed above per this email.

Thank you,

Ashley

From: James Stors <James_Stors@waters.com>
Sent: Wednesday, August 12, 2020 3:03 PM
To: Ashley Deschenes <Ashley_Deschenes@waters.com>
Subject: VAF's for TE82760, TE82882, TE82903, TE82964, TE82969, and TE83057 Systems

Hi Ashley,

Attached are the VAF's for the Premier Project Detector Systems.

Regards,
Jim

1. PURPOSE

The purpose of this Validation Assessment Form (VAF) is to document the assessment of an engineering change to the TE82964, 2489 ACQUITY TUV Pre-test Download Station, and to define the resulting deliverables required to maintain the system process validation.

2. BACKGROUND

The TE82964, 2489 ACQUITY TUV Pre-test Download Station, is designed to download instrument firmware and assign the instrument serial number for 2489 and ACQUITY TUV Detectors:

The UUT is connected to a custom test box that simulates a leak and uses HyperTerminal to download a Serial Number to the UUT. The system does not have custom software, nor does it print a Test Record.

3. DESCRIPTION OF CHANGE

- 3.1.** A new TSP (735005108, Acquity Premier TUV Firmware Download/Pretest Test and Specification Procedure) is being released for the TE82964 program in order to add part number 186018006, Acquity Premier TUV Assembly, and the Warranty and Repair equivalent part number, 800000534.

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
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, 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. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.2. 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?	☒	☐
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4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☐	☒
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the local site?	☒	☐

4.3. This change results in a Medium Risk Assessment and the associated process validation requirements, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

No hazards are potentially introduced to the environment, Operator, Assembler, Service Engineer, or End User; due to this change.

6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

6.1. 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?	☒	☐
Comments/Justification This change is a part number add and does not affect the design or control of the system.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change?	☐	☒
Comments/Justification This change results in the need to perform a partial Installation Qualification (IQ) execution on each TE82964 system. The partial IQ execution shall include Test Script IQ-01, Associated Documentation Verification Test Script Data Sheet in order to verify the status of the new Test and Specification Procedure (TSP), 735005108, in SAP, and Test Script IQ-06, Functional Verification, to ensure Firmware loading to the new part numbers. The system facilities/install site, Preventive Maintenance, Firmware Verification, and safety were previously qualified and are not affected by this change.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change?	☒	☐
Comments/Justification The change does not affect the external measurement equipment and does not involve Operator influence.		

6.4. 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.)	☒	☐
Comments/Justification 100% critical to quality (CTQ) attributes verified.		

6.5. 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.		

6.6. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- TSP 735005108 shall be written to add the additional ACQUITY TUV part numbers to the system capability.
- Coordination with the Production areas shall be used to limit the number of down systems at any given time to minimize impact on production schedules.
- An Operator from each Production Area shall be trained to the TSP and shall perform the testing for IQ-06, Functional Verification Test Script.