

For the 2690 Pump Tray Tester (TE82526)

PREPARED BY

Name	Role	Signature	Date
Emma Pierce	Test Validation Engineer		29 Jan 2020

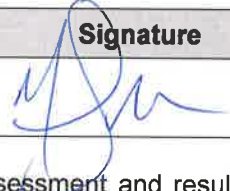
The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

REVIEWED BY

Name	Role	Signature	Date
Mark Jussuame	Senior Test Engineer		30 Jan 2020

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
Megan Marshall	Sr. Quality System Engineer		31 Jan 2020

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

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the 2690 Pump Tray Tester (TE82526) and to define the resulting deliverable(s) required to maintain the system process validation.

2. BACKGROUND

The 2690 Pump Tray Tester (TE82526) verifies the pressure and flow rates of pump trays of the following part numbers: 279000419, 279000524, 289000526, WAT270463, and WAT271078, and the equivalent spare part numbers. Upon completion of all testing a record is automatically generated and printed for the operator to collect.

3. DESCRIPTION OF CHANGE

The three 2690 Pump Tray Testers at the Flextronics Contract Manufacturing Site in Singapore (TE82526, TE82526-1, and TE82526-4) are being retrofitted with new valves in the test box and new computers; these computers will run on Windows 10. The replacement valves are not identical but are functionally equivalent. This is a hardware change that does not change the way the system controls or measures a test specification or PSC result. The custom test software is being installed on the new PCs; the change in operating system does not require any changes to the test software.

An additional 2690 Pump Tray Tester (TE82526-2) is being deployed to the Flextronics Contract Manufacturing Site in Singapore. This system will be delivered and installed with the new valve and PC running Windows 10.

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?	☒	☐

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?	☒	☐

This change results in a High risk assessment for the additional 2690 Pump Tray Tester (TE82526-2) and a Medium risk assessment for the other three 2690 Pump Tray Testers (TE82526, TE82526-1, and TE82526-4). This change results in the associated process validation requirements for each, as detailed in Section 6.0.

5. HAZARD ASSESSMENT:

There are no hazards potentially introduced to the environment, operator, assembler, service technician 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

An EDV is not required because this change does not affect the way the system controls or measures a specification or PSC result.

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

A full Installation Qualification will be performed using the Installation Qualification Protocol 730004135 for all four 2690 Pump Tray Testers located at the Flextronics Contract Manufacturing Site in Singapore.

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

A TMV is not required because there is no change to measurement equipment and this change 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 An OQ is not required because 100% of critical to quality attributes are 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 A PQ is not required because 100% of critical to quality attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation or facilities/ utilities. The additional system TE82526-2 will be added to the Calibration/ Preventative Maintenance database at Flextronics.
- There is no impact to any other qualified, verified, or validated process, test method, or equipment.
- The impact on production schedules will be low.
- The systems will be updated, the additional system will be installed, and all qualification activities will be executed by Flextronics personnel with guidance from Test Engineering and Validation Engineering as appropriate.
- No additional training will be required.