For the 2690 Pump Tray Tester (TE82526)

PREPARED BY

Name	Role	Signature	Date
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The "Prepared By" signature denotes that this document accurately describes the qualification activities.

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APPROVED BY

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The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

VERSION:	00	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
SUMMARY OF CHANGE: First document for approval					

1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of Test Specification and Procedure, Alliance Pumptray WAT210700, Rev 09 for the TE82526, the 2690 Pump Tray Tester.

2.0 SYSTEM BACKGROUND

The TE82526, the 2690 Pump Tray Tester, facilitates the functional test of the following part numbers: 279000419, 279000524, 289000526, WAT270463, WAT271078, and the equivalent spare part numbers. Upon completion of all testing, a record is automatically generated and printed for the operator to collect.

This 2690 Pump Tray Tester TE82526 at the Flextronics Contract Manufacturing Site in Singapore is being retrofitted with new valves in the test box and new computer; This computer 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 PC; the change in operating system does not required any changes to the test software. This system will be delivered and installed with the new valve and PC running Windows 10.

3.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82526, the 2690 Pump Tray Tester, based on the requirements of the executed protocol, the Installation Qualification Protocol, 730004135 Ver. 03 as detailed in TE82526-29JAN2020-VAF.

4.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82526, the 2690 Pump Tray Tester was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE82526, the 2690 Pump Tray Tester complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the TE82526, the 2690 Pump Tray Tester can be considered fully qualified and fit for intended use.

5.0 DEFINITIONS / ABBREVIATIONS

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
TSP	Test Specification and Procedure
CAL/PM	Calibration/Preventive Maintenance
S/N	Serial Number
P/N	Part Number
VAF	Validation Assessment Form
Hz	Hertz
N/A	Not Applicable
SAP	Enterprise Resource Planning Software
UUT	Unit Under Test
VAC	Volts Alternating Current
EQID	Equipment Qualification Identification
ANSI	American National Standards Institute

Term	Explanation
PSC	Production Support Checks

6.0 TRAINING

The operator of the TE82526, the 2690 Pump Tray Tester was trained according to the Test Specification and Procedure, Alliance Pumptray WAT210700, Rev 09. The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. Both Training records are provided as Attachments 7.1 and 7.2, respectively.

7.0 QUALIFICATION Results

7.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

7.1.1 The Test Specification and Procedure, Alliance Pumptray WAT210700, Rev 09 was confirmed to be in SAP with a status of Release General, as evidenced below:

Document List After Selection 11 Hits

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RevL...	Type	Document	Vs	Part	Description	Status text	Current Ve	Valid From	Valid To	Change No.	Long name
05	MSC	WAT210700	05	000	TEST PROC., 2690 PUMP TRAY TESTER	RELEASE GENERAL		03.07.2002	31.12.9999	9000280	PLM MIGRA...
00	TSP	WAT210700	00	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		11.08.1998	28.10.1998	ECO3831	Production ...
01	TSP	WAT210700	01	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		29.10.1998	23.02.1999	ECO4099	Production ...
02	TSP	WAT210700	02	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		24.02.1999	14.06.2000	ECO4523	Production ...
03	TSP	WAT210700	03	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		15.06.2000	21.02.2001	ECO06593	Production ...
04	TSP	WAT210700	04	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		22.02.2001	20.06.2001	ECO07629	Rosely Dow...
05	TSP	WAT210700	05	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		21.06.2001	02.06.2003	ECO08175	Rosely Dow...
06	TSP	WAT210700	06	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		03.06.2003	30.11.2014	9104161	Wendy Harr...
07	TSP	WAT210700	07	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		01.12.2014	08.06.2015	9193357	Michael Cot...
08	TSP	WAT210700	08	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		09.06.2015	08.05.2016	9198230	Michael Cot...
09	TSP	WAT210700	09	000	TEST SPEC/PROC,M2690 PUMP TRAY W&W/O...	RELEASE GENERAL		09.05.2016	31.12.9999	9207008	Michael Cot...

7.2 Test Script IQ-02: Site Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.4.

7.2.1 The ambient temperature and humidity were measured using Temperature/Humidity Meter and were determined to be within specification as defined by the Performance Specification, Pump Mechanics Assembly, WAT270698. The calibration record is provided as Attachment 7.5.

7.2.2 The electrical supply was measured using a Multimeter and was determined to be within specification as defined by the Performance Specification, Pump Mechanics Assembly, WAT270698. The calibration record is provided as Attachment 7.6.

7.2.3 The Test Station was confirmed to have more than the four (4) dedicated electrical outlets and minimum of 1 dedicated network required. Picture of dedicated electrical outlets and network port is provided as Attachment 7.7.

7.2.4 The space and test bench of the TE82526, the 2690 Pump Tray Tester were confirmed to have adequate space for testing and service. The bench was confirmed to be large and strong enough to support all test equipment. Picture of the Test Station work area is provided as Attachment 7.8.

7.3 Test Script IQ-03: Instrumentation Calibration Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed script is provided as Attachment 7.9.

7.3.1 The Electronics Weigh Balance of the TE82526, the 2690 Pump Tray Tester was confirmed to have had calibration within this time frame. The most recent calibration certificate is provided as Attachment 7.10.

7.3.2 The TE82526, the 2690 Pump Tray Tester was confirmed to be in the Preventive Maintenance Master Schedule with a six (6) month maintenance cycle. A screen capture from the database is provided as Attachment 7.11.

7.4 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification

Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.12.

7.4.1 The Test Equipment Software version listed in the TSP is Test Software 1.0 and was verified to match the version listed on the test equipment display. The objective evidence was provided as Attachment 7.13.

7.4.2 This test station does not download firmware.

7.5 Test Script IQ-05: General Safety and Alarms was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.14.

7.5.1 It was confirmed that there were no mechanical safety pinch points or sharp edges. Picture of tester station safety check is provided as Attachment 7.15

7.6 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.16.

7.6.1 One (1) UUTs was tested using the TE82526, the 2690 Pump Tray Tester with all tests passing. The test record is provided as Attachment 7.17.

7.7 This table provides a summary of each test script as performed according to 730004135, Ver. 03 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3	None
IQ-02	Pass	Attachments 7.4, 7.5, 7.6, 7.7, and 7.8	None
IQ-03	Pass	Attachments 7.9, 7.10, and 7.11	None
IQ-04	Pass	Attachments 7.12 and 7.13	None
IQ-05	Pass	Attachments 7.14 and 7.15	None
IQ-06	Pass	Attachment 7.16, and 7.17	None

8.0 ATTACHMENTS

8.1 Completed Operator Training Record WAT210700, Rev 09

8.2 Completed Executor Training Record 730004135, Ver. 03

8.3 Completed Test Script IQ-01: Associated Document Verification

8.4 Completed Test Script IQ-02: Site Verification

8.5 Objective Evidence IQ-02: Temperature/Humidity Meter Calibration Record and Measurement Record

8.6 Objective Evidence IQ-02: Multimeter Calibration Record and Measurement Record

8.7 Objective Evidence IQ-02: Picture of dedicated electrical outlets and network port

8.8 Objective Evidence IQ-02: Picture of Test Station Work Area

8.9 Completed Test Script IQ-03: Instrument Calibration Verification

8.10 Objective Evidence IQ-03: Electronics Weigh Balance Calibration Record

8.11 Objective Evidence IQ-03: Screen Capture of Preventive Maintenance Master Schedule

8.12 Completed Test Script IQ-04: Test Software and Instrument Firmware Version

8.13 Objective Evidence IQ-04: Test Software version on Cover Page of TSP WAT210700 and on Test Equipment

8.14 Completed Test Script IQ-05: General Safety and Alarms

8.15 Objective Evidence IQ-05: Picture of tester station safety check

8.16 Completed Test Script IQ-06: Functional Verification

8.17 Objective Evidence IQ-06: Test Records for UUT P/N: 289000525 (S/N: 06L0H071)

9.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the Installation Qualification Protocol 730004135, Ver. 03.

10.0 References

The current approved versions of the following documents are referenced within this report:

Document Number	Document title
730004135, Ver. 03	Installation Qualification Protocol
WAT210700, Rev 09	TEST SPECIFICATION AND PROCEDURE, ALLIANCE PUMPTRAY
WAT270698, Rev A	PERFORMANCE SPECIFICATION, Pump Mechanics Assembly
WAT046538, Ver. 12	Generic Electrical Safety Test Procedure
ANSI C84.1	Voltage Tolerance Standard
TE82526-29JAN2020-VAF	Validation Assessment Form for the 2690 Pump Tray Tester