

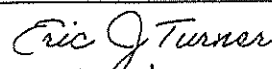
Waters THE SCIENCE OF WHAT'S POSSIBLE.™	Validation Assessment Form
Document #: TE82882-10SEP19-VAF	SAP #: TE0082882QX

VALIDATION ASSESSMENT
For the TE82882 – PDA Detector Final Station

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		12 Sep 2019

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principle Test Engineer		13 SEP 2019
Chan Yee Hwa	Manufacturing Engineer		16 SEP 2016 16 SEP 2019

VH 18 SEP 19
Data Entry Error

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		18 Sep 2019

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

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the TE82882 PDA Detector Final Test Stations.

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

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1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the released PDA Detector Final Test Stations (TE82882). This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

The ACQUITY Arc Bio 2998 PDA Detector Final Test Station, TE82882, is used to verify functionality of the Photo Diode Array (PDA) Detector via controlled noise and drift tests.

The TE82882 automated test station is capable of testing the following Waters LC Part Numbers per the associated TSP:

TSP 735001613: 186002998, 186015026, 186015030, 186015032, 186015033, 186015034, 186015053, 186017003, 186017013, 186299800, 279002655, 700002787, 700003765, 700004035, 700005424, 700005427, 700009014, 700009328, 700009532, 700011650, 700011652, 700011867, 700011868, 700011869, 700012243, 700012245, 800000202, 800000244, 800000245, 800000304, 800000305, 800000397, 800000414, 800000439, 800000453, 800000476, N2971013 and N2971035

3. DESCRIPTION OF CHANGE

3.1. UPDOB2 and 3 are arbitrary labels used in the PDAIni.txt file. The spare part number cannot be tested due to wrong arbitrary labels used in PDAIni.txt file. In order to run spare part number 700011652 testing on PDA Detector Final Test Station, changed this arbitrary label from UPDOB2 to UPDOB3 by editing PDAIni.txt file. UPDOB3 is a fine label if it is a PDA optics bench (UPD = PDA OB = optics bench). The source code need not change. The system software version is not being modified based on this change as the part numbers are defined through an access-level controlled text file PDAIni.txt.

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?	☒	☐

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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 Milford site?	☒	☐

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

5. HAZARD ASSESSMENT:

No known hazard impact to the environment, operator, assembler, service technician and end user due to the 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? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This correction is only to edit the PDAInit.txt file that can be detected by the system using the existing software. The change does not affect the software, 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? (Justify partial execution in the Comments/Justification section below.)	☒	☐

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Comments/Justification
 This correction does not affect software, design or control of the system, so no IQ is recommended. The affected part number will be tested on each of system after changed to verify the correct part number is indicated on the Test Record and the appropriate tests were run.
 This change affects TE82882-8, TE82882-9, TE82882-10, TE82882-11, TE82882-13, and TE82882-14 located in Flextronics contract manufacturing site of WPPL
 The Objective Evidence of the Test Records for the new part numbers for each station shall be provided as Attachments and routed for approval using the Validation Assessment Objective Evidence Routing Sheet provided at the end of this VAF.

6.3. 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 The system does not utilize external 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 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.

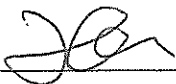
7. IMPLEMENTATION ASSESSMENT:

- TSP 735001613 is not required to be revised as this change is to correct the arbitrary labels in an access-level controlled text file
- This change is impacting production as spare part number 700011652 tested using the systems will not be able to ship (they will be quarantined) post the change being made until the functional testing is executed for all systems and the objective evidence is routed using the Validation Assessment Objective Evidence Routing Sheet.
- The functional tests will be run for spare part number 700011652 on each system and provided to Validation Engineering as objective evidence. The objective evidence shall be routed for approval using the Validation Assessment Objective Evidence Routing Sheet.

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**VALIDATION ASSESSMENT
OBJECTIVE EVIDENCE COMPLETION**
For the TE82882 – PDA Detector Final Station

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		24 SEP 2019

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principle Test Engineer		
Chan Yee Hwa	Manufacturing Engineer		24 SEP 2019

APPROVED BY

Name	Role	Signature	Date
Tan Kah Chin	Senior Quality Assurance Manager		

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The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the TE82882 PDA Detector Final Test Stations.

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ATTACHMENTS:

Attachment 1: TE82882-8 Test Record for 700011652

Attachment 2: TE82882-9 Test Record for 700011652

Attachment 3: TE82882-10 Test Record for 700011652

Attachment 4: TE82882-11 Test Record for 700011652

Attachment 5: TE82882-13 Test Record for 700011652

Attachment 6: TE82882-14 Test Record for 700011652

Waters Corporation - Test Record

Part Number: **700011652**

Product: PDA Optics Bench 3

Operator: 246154

Start Time: 09/24/2019, 11:26:

Serial Number: 34K8U024

End Time: 09/24/2019, 13:07:

Test System: **TE82882-8**

Order: N/A

Test Software: 4.2

Location: Flextronics, SG

TMD: N/A

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	26.98	40	Degrees C	PASS
Hot Baseline (Audit)	20	28.13	40	Degrees C	PASS
F1 alone (Audit)	20	29.57	40	Degrees C	PASS
F1 and F2 (Audit)	20	26.38	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	118728	250000	counts	PASS
Total Runs	0	5	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	4.33	7	uAu	PASS
Final Drift	-1000	-33	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

24 SEP 2019

END OF DATA

Document No.: TE82882-10SEP19-VAF
Iteration No.: N/A
Attachment: 1 Page: 1 of 1

Waters Corporation - Test Record

Part Number: **700011652**

Product: PDA Optics Bench 3

Operator: 246154

Start Time: 09/20/2019, 14:44:

Serial Number: 34K8U024

End Time: 09/20/2019, 16:25:

Test System: **TE82882-9**

Order: N/A

Test Software: 4.2

Location: Flextronics, SG

TMD: N/A

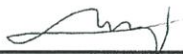
Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	24.61	40	Degrees C	PASS
Hot Baseline (Audit)	20	25.04	40	Degrees C	PASS
F1 alone (Audit)	20	26.19	40	Degrees C	PASS
F1 and F2 (Audit)	20	24.58	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	118853	250000	counts	PASS
Total Runs	0	5	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	4.05	7	uAu	PASS
Final Drift	-1000	-751	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

20 SEP 2019

END OF DATA

Document No.:

TE82882-10SEP19-VAF

Iteration No.:

N/A

Attachment:

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Waters Corporation - Test Record

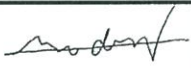
Part Number: <u>700011652</u>	Product: <u>PDA Optics Bench 3</u>
Operator: <u>246154</u>	Start Time: <u>09/20/2019, 10:55:</u>
Serial Number: <u>34K8U024</u>	End Time: <u>09/20/2019, 13:30:</u>
Test System: <u>TE82882-10</u>	Order: <u>N/A</u>
Test Software: <u>4.2</u>	Location: <u>Flextronics, SG</u>

TMD: N/A

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	23.53	40	Degrees C	PASS
Hot Baseline (Audit)	20	24.11	40	Degrees C	PASS
F1 alone (Audit)	20	24.93	40	Degrees C	PASS
F1 and F2 (Audit)	20	23.59	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	113085	250000	counts	PASS
Total Runs	0	8	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	4.53	7	uAu	PASS
Final Drift	-1000	214	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed: <u>246154</u> 	Date: <u>20 SEP 2019</u>
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END OF DATA

Document No.: TE82882-10SEP19-VAF
 Iteration No.: N/A
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Waters Corporation - Test Record

Part Number: 700011652

Product: PDA Optics Bench 3

Operator: 246154

Start Time: 09/23/2019, 14:14:

Serial Number: 34K8U024

End Time: 09/23/2019, 15:19:

Test System: TE82882-11

Order: N/A

Test Software: 4.2

Location: Flextronics, SG

TMD: N/A

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	26.92	40	Degrees C	PASS
Hot Baseline (Audit)	20	27.99	40	Degrees C	PASS
F1 alone (Audit)	20	29.23	40	Degrees C	PASS
F1 and F2 (Audit)	20	26.63	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	120758	250000	counts	PASS
Total Runs	0	2	24		PASS
Noise Runs	0	2	5		PASS
Final Noise	0	5.03	7	uAu	PASS
Final Drift	-1000	488	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

23 SEP 2019

END OF DATA

Document No.:

TE82882-10SEP19-VAF

Iteration No.:

N/A

Attachment:

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Waters Corporation - Test Record

Part Number: 700011652

Product: PDA Optics Bench 3

Operator: 246154

Start Time: 09/23/2019, 15:47:

Serial Number: 34K8U024

End Time: 09/23/2019, 17:46:

Test System: TE82882-13

Order: N/A

Test Software: 4.2

Location: Flextronics, SG

TMD: N/A

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	26.52	40	Degrees C	PASS
Hot Baseline (Audit)	20	27.27	40	Degrees C	PASS
F1 alone (Audit)	20	28.64	40	Degrees C	PASS
F1 and F2 (Audit)	20	26.1	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	119942	250000	counts	PASS
Total Runs	0	6	24		PASS
Noise Runs	0	2	5		PASS
Final Noise	0	5.53	7	uAu	PASS
Final Drift	-1000	-815	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

23 SEP 2019

END OF DATA

Document No.: TE82882-10SEP19-VAE
 Iteration No.: N/A
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Waters Corporation - Test Record

Part Number: **700011652**

Product: PDA Optics Bench 3

Operator: 246144

Start Time: 09/23/2019, 10:54:

Serial Number: 34K8U024

End Time: 09/23/2019, 14:06:

Test System: **TE82882-14**

Order: NA

Test Software: 4.2

Location: Flextronics, SG

TMD: NA

Firmware: 1.70 Build#: 6367 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Baseline Temperature (Audit)	20	21.06	40	Degrees C	PASS
Hot Baseline (Audit)	20	21.27	40	Degrees C	PASS
F1 alone (Audit)	20	21.75	40	Degrees C	PASS
F1 and F2 (Audit)	20	21.82	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	187.2751	188	nM	PASS
Lambda512	501.25	502.9983	511.25	nM	PASS
Shunt/Cell energy 5ms	80000	111372	250000	counts	PASS
Total Runs	0	10	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	6.05	7	uAu	PASS
Final Drift	-1000	-631	1000	uAu	PASS

PDA Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

23 SEP 2019

END OF DATA

Document No.: TE82882-10SEP19-VAF
Iteration No.: N/A
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