

 THE SCIENCE OF WHAT'S POSSIBLE.™		Installation Qualification Report	
Report No: TE82882-10-IQR	Iteration No: 02	SAP No: TE008288210	

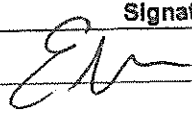
INSTALLATION QUALIFICATION REPORT

For the 2998 Final Test System (TE82882-10)

PREPARED BY

Name	Role	Signature	Date
Luo HuaZhen	Senior Test Engineer		04 Jul 2019

REVIEWED BY

Name	Role	Signature	Date
Eric Turner	Principal Test Engineer		26 July 2019

APPROVED BY

Name	Role	Signature	Date
Kah Chin Tan	Senior Quality Assurance Manager		29 Jul 2019

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

The "Reviewed By" signature denotes agreement with the description of the qualification activities.

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

REVISION HISTORY

Version	Author	Summary of change
00	Emma Pierce	First document for approval.
01	James J. Stors	New software version to print serial number in the Report footer.
02	Luo HuaZhen	New software version to add Optics Bench part numbers

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1.0 Purpose

The 2998 Final Test System, TE82882-10, is located in Singapore at contract manufacturer Flextronics. The 2998 Final Test System is used to perform functionality testing of Waters Corporation's 2998 Photo Diode Arrays (PDA's) as defined in TSP 735001613, to ensure compliance to the defined Manufacturing Test Specifications.

The system uses serial ports to communicate to up to four (4) UUT's in order to test Noise, Drift, and Optics. Upon completion a Final Test Record is automatically generated and a hard copy is printed. In addition, the Final Test Record is sent to the SigmaProd Server.

2.0 Scope of Report

This Test Equipment Report details the IQ activities undertaken for the 2998 Final Test System (TE82882-10) based on the requirements of the performed Installation Qualification, 730004135, Version 02 as outlined by the Test Software Version 4.2 risk assessment, per TE82882-10JUN19-VAF.

The risk assessment, based on this change, resulted in the requirement of performing the following test scripts:

- IQ-01 Associated Documentation Verification: To verify that the PDA Final Test System Test and Specification Procedure, 735001613, that references the new software version, 4.2, is in the appropriate state in SAP.
- IQ-04 Test Software Version: To verify the version specified within the PDA Final Test, Test and Specification Procedure, 735001613, matches the version of the program.
- IQ-06 Functional Verification: To verify that the entered UUT Serial Number is correctly listed at the bottom of the Test Record.

All other testing performed, as detailed in TE82882-10-IQR, Iteration 00, remains valid and applicable as there is no change to the installation site, calibration and PM schedule, or the safety and alarms.

3.0 Summary of Results - Statement of Fitness for Intended Use

The 2998 Final Test System (TE82882-10) was tested in accordance with the applicable sections of the Installation Qualification Protocol, 730004135, Version 02, as outlined in the Test Software Version 4.2 risk assessment, per TE82882-10JUN19-VAF. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the 2998 Final Test System (TE82882-10) remains compliant with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the 2998 Final Test System (TE82882-10) remains fully qualified and fit for intended use post the change, as outlined in TE82882-10JUN19-VAF.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
IQ	Installation Qualification
IQR	Installation Qualification Report
UUT	Unit Under Test
PDA	Photo Diode Array
SAP	Enterprise Resource Planning (ERP) software
TSP	Test Specification and Procedure
PM	Preventive Maintenance
VAC	Volts Alternating Current
Hz	Hertz
°C	Degrees Celsius
N/A	Not Applicable

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5.0 Training

The Executor who performed the 2998 Final Test System (TE82882-10) Installation Qualification was trained according to the Installation Qualification Procedure, 730004135, Version 02. The training record is proved as Attachment 7.1.

The Operator who performed the testing of the UUT using the 2998 Final Test System (TE82882-10) per Installation Qualification Procedure, 730004135, Version 02, IQ-06, Functional Verification Test Script, has been trained to the updated PDA Final Test System Test and Specification Procedure, 735001613, Version 22. The Training Record is provided as Attachment 7.2.

6.0 Qualification Results

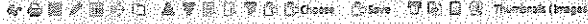
- 6.1 Test Script IQ-01, Associated Documentation Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the PDA Final Test System Test and Specification Procedure, 735001613, as outlined in TE82882-10JUN19-VAF.
- 6.1.1 IQ-01, Associated Documentation Verification Data Sheet, is provided as Attachment 7.3.
- 6.1.2 The updated PDA Final Test System Test and Specification Procedure, 735001613, Version 22, was confirmed to have been updated with software version 4.2 and to be in SAP with a status of Ready. A screen capture is provided below:

Document List After Selection

24 Hits

Waters





RevL	Type	Document	Vs Part	Description	Status text	Current	Valid From	Valid To	Change No.	Long name
Select All	TSP	735001613	00 000	Acquity PDA Final Test	RELEASE GENERAL		25.06.2007	30.03.2008		Eric Turner
	TSP	735001613	01 000	Acquity PDA Final Test	ABANDON					Bruce Porter
B	TSP	735001613	02 000	Acquity PDA Final Test	RELEASE GENERAL		31.03.2008	11.05.2008	9124035	Eric Turner
C	TSP	735001613	03 000	Acquity PDA Final Test	RELEASE GENERAL		12.05.2008	09.07.2008	9124937	Eric Turner
D	TSP	735001613	04 000	PDA Final test	RELEASE GENERAL		10.07.2008	03.12.2008	9126327	Eric Turner
E	TSP	735001613	05 000	PDA Final test	RELEASE GENERAL		04.12.2008	29.03.2009	9130040	Eric Turner
F	TSP	735001613	06 000	PDA Final test	RELEASE GENERAL		30.03.2009	21.05.2009	9140911	Eric Turner
G	TSP	735001613	07 000	PDA Final test	RELEASE GENERAL		22.05.2009	01.07.2010	9142852	Eric Turner
H	TSP	735001613	08 000	PDA Final test	RELEASE GENERAL		02.07.2010	22.11.2010	9153554	Eric Turner
J	TSP	735001613	09 000	PDA Final test	RELEASE GENERAL		23.11.2010	04.07.2012	9157158	Chris Green
	TSP	735001613	10 000	PDA Final test	ABANDON					Eric Turner
K	TSP	735001613	11 000	PDA Final test	RELEASE GENERAL		05.07.2012	09.02.2014	9171410	Eric Turner
L	TSP	735001613	12 000	PDA Final test	RELEASE GENERAL		10.02.2014	16.02.2014	9185711	Chris Green
M	TSP	735001613	13 000	PDA Final test	RELEASE GENERAL		19.02.2014	12.10.2014	9186532	Eric Turner
N	TSP	735001613	14 000	PDA Final test	RELEASE GENERAL		13.10.2014	24.03.2015	9192039	Eric Turner
	TSP	735001613	15 000	PDA Final test	ABANDON					Eric Turner
P	TSP	735001613	16 000	PDA Final test	RELEASE GENERAL		25.03.2015	12.07.2015	9195587	Eric Turner
R	TSP	735001613	17 000	PDA Final test	RELEASE GENERAL		13.07.2015	10.12.2015	9198916	Eric Turner
T	TSP	735001613	18 000	PDA Final test	RELEASE GENERAL		11.12.2015	28.11.2017	9202728	Tyler Model
U	TSP	735001613	19 000	PDA Final test	RELEASE GENERAL		29.11.2017	09.09.2018	9218596	Eric Turner
V	TSP	735001613	20 000	PDA Final test	RELEASE GENERAL		10.09.2018	06.12.2018	9224731	Eric Turner
W	TSP	735001613	21 000	PDA Final test	RELEASE GENERAL		07.12.2018	31.12.9999	9226454	Eric Turner
	TSP	735001613	22 000	PDA Final test	READY					Eric Turner
	TSP	735001613	23 000	PDA Final test	ABANDON					Eric Turner

- 6.1.3 The PDA Linearity Test System Preventive Maintenance Procedure, 735003030, Version 00/Revision A, was confirmed to be in SAP with a status of Release General. A screen capture is provided below:

Document List After Selection

1 Hits

Waters



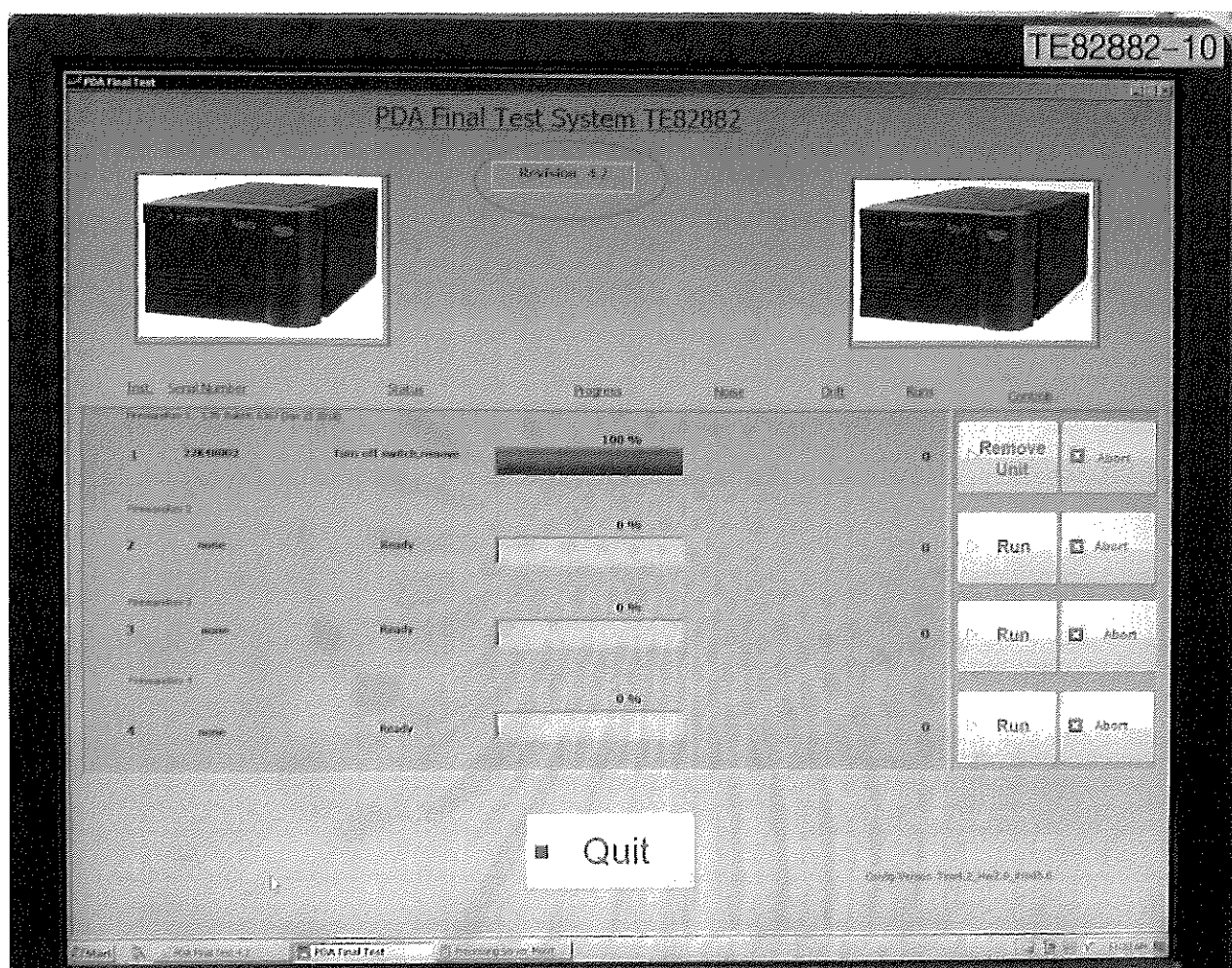


RevL	Type	Document	Vs Part	Description	Status text	Current	Valid From	Valid To	Change No.	Long name
A	CAL	735003030	00 000	PDA FINAL TESTER PREVENTATIVE MAINTENANC	RELEASE GENERAL		12/05/2013	12/31/9999	9182132	Eric Turner

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6.2 Test Script IQ-04, Test Software and Instrument Firmware Version, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the updated software version 4.2, as outlined in TE82882-10JUN19-VAF.

- 6.2.1 IQ-04, Test Software and Instrument Firmware Version Data Sheet, is provided as Attachment 7.4.
- 6.2.2 The Test Equipment Software version listed in 735001613, PDA Final Test System Test and Specification Procedure (Version 22), is 4.2 and was verified to match the revision (listed as Revision on the Operator Interface) displayed on the Test Equipment PDA Final Test System TE82882 program display, as shown in the screen capture below:



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- 6.3 Test Script IQ-06, Functional Verification, was performed in accordance with Installation Qualification Protocol, 730004135, Version 02, for the updated software version 4.2, as outlined in TE82882-10JUN19-VAF.
- 6.3.1 IQ-06, Functional Verification Data Sheet is provided as Attachment 7.5.
 - 6.3.2 One (1) UUT, Part Number 700012243, was tested using the TE82882-10, 2998 Final Test System, and met the requirement of obtaining a Final Test Record with the UUT Serial Number correctly listed at the bottom of the Test Record.
 - 6.3.2.1 The Instrument Final Test Record is provided as Attachment 7.6.
 - 6.3.3 One (1) UUT, Part Number 700012245, was tested using the TE82882-10, 2998 Final Test System, and met the requirement of obtaining a Final Test Record with the UUT Serial Number correctly listed at the bottom of the Test Record.
 - 6.3.3.1 The Instrument Final Test Record is provided as Attachment 7.7.

- 6.4 A summary of the attached objective evidence that applies to each Test Script is provided in the Table below:

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachment 7.3	None
IQ-04	Pass	Attachment 7.4	None
IQ-06	Pass	Attachment 7.5, 7.6 and 7.7	None

7.0 Attachments

- 7.1 Completed Executor Training Record 730004135, Ver.02
- 7.2 Completed Operator Training Record 735001613, Ver.22
- 7.3 IQ-01, Associated Documentation Verification Test Script Data Sheet
- 7.4 IQ-04, Test Software and Instrument Firmware Version Test Script Data Sheet
- 7.5 IQ-06, Functional Verification Test Script Data Sheet
- 7.6 Instrument Final Test Record for IQ-06, Part Number: 700012243, Serial Number: 22K6P003
- 7.7 Instrument Final Test Record for IQ-06, Part Number: 700012245, Serial Number: 22K4B002

8.0 Deviation from Test Equipment Qualification

There were no deviations generated during the execution of the Installation Qualification, 730004135, Version 02, for the 2998 Final Test System (TE82882-10), as outlined in the Test Software Version 4.2 risk assessment, per TE82882-10JUN19-VAF.

9.0 References

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

Document Number	Document title
730004135	Installation Qualification Protocol
735001613	PDA Final Test System Test and Specification Procedure
735003437	PDA Linearity Test System Preventive Maintenance Procedure
TE82882-10JUN19-VAF	Test Software Version 4.2 risk assessment

Title: individual Training Form

Document No: 730002657

Version No: 00

Page 1 of 1

Training Type:	Read and Understood		
Name:	Luo HuaZhen	Employee ID¹	618078
Date of Training	01Mar2019		
Comments:	N/A		

Document Number	Title	Rev. #
730004135	Installation Qualification Protocol	02
N/A JE 01Mar2019		


Senior Test Engineer
01Mar2019
 Employee's Signature Title Date

N/A self Trained
01Mar2019
 Trainer's Signature Title Date

Document No.: TE82882-10-JQR
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¹ Without preceding "90"

Document #	735001613	Document Title	PDA Final Test - Test and Specification Procedure	Version	22
				Revision	N/A

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

[illegible]

Document No.: TE82882-10-LVR
Iteration No.: 02
Attachment: 22 Page: 1 of 1

Title: Installation Qualification Protocol

Document # 730004135

Version # 02

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Test Script # IQ-01	IQ Test Name: Associated Documentation Verification		
Equipment # TE82882-10	Equipment Name: PDA Final Test System		
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore			
Purpose: To verify that supporting documentation is available prior to the completion of qualification.			
Test Execution: - List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header, then complete the table below. Rows may be added/removed as needed. - All applicable documents must have a status of Ready, Pre-Rel-Prod, or Release General in SAP. If applicable documents are unavailable in SAP state why in the comments section.			
Objective Evidence: - Completed IQ-01 Test Script Data Sheet - SAP screenshots of below available document(s)			
Document Type	Title, Doc. #, Version/Revision #	Status in SAP	Initial & Date
TSP	PDA Final Test - Test and Specification Procedure; 735001613; Version 22	Ready	HZ 02Jul2019
Comments: 			
Overall Test Conclusion ☒ Pass ☐ Fail		Document No.: TE82882-10-IQR Iteration No.: 02 Attachment: 7.3 Page: 1 of 1	

Title: Installation Qualification Protocol

Document # 730004135

Version # 02

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82882-10	Equipment Name:	PDA Final Test System		
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore					
Purpose: To verify that the installed software/firmware is correct per the applicable design and/or operational document(s).					
Test Execution: - List all relevant Equipment software and/or instrument firmware in the Description column. Specify the associated part number for the instrument firmware, if applicable. Rows may be added/removed as needed. - List the associated required equipment software and/or critical instrument/internet connection sharing firmware version(s), as defined in the applicable design/operational document(s), in the Acceptance Criteria column. - Verify that the software version displayed on the Operator Interface of the program and/or the firmware loaded on the instruments/PC match the acceptance criteria identically, if applicable, then complete the table below.					
Objective Evidence: - Completed IQ-04 Test Script Data Sheet - Identify and/or provide a screen capture/print out/copy of the applicable design/operational document that defines the required software/firmware version(s) within or as an attachment to the associated Installation Qualification Report. - Screen capture and/or test record displaying/indicating the software and/or firmware version(s), as applicable					
Description	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Equipment Software	Version: 4.2	Version: 4.2	Pass	HZ 02Jul2019	
Comments: N/A JE 02Jul2019					
Overall Test Conclusion			Document No.: <u>TE82882-10-IQR</u> Iteration No.: <u>02</u> Attachment: <u>7.4</u> Page: <u>1</u> of <u>1</u>		
☒ Pass			☐ Fail		

Test Script # IQ-06	IQ Test Name: Functional Verification		
Equipment # TE82882-10	Equipment Name: PDA Final Test System		
Installation Site: Flextronics Contract Manufacturing Site of WPPL in Singapore			
Purpose: To verify that the system operates as expected.			
Test Execution: - Select the UUT(s) or tests to be performed as defined within the Installation Qualification Section of 730001835. - List the Part Number and Serial Number, if applicable, in the UUT Part Number/Serial Number column. - Define the appropriate Acceptance Criteria within the Acceptance Criteria column. - Perform a test of the UUT(s), verify the Acceptance Criteria, then complete the table below. If an associated Test Record is being used as objective evidence the Header/Footer information should be verified for accuracy.			
Objective Evidence: - Completed IQ-06 Test Script Data Sheet - Copy of the Test Record(s) for the UUT(s), as applicable - The UUT(s) selected for this Test Script and the reasoning for why it/they were selected shall be summarized within the associated Installation Qualification Report. - If this Acceptance Criteria is other than "All required CTQ Specification measurements result in a Pass" then it shall be summarized within the associated VAF, Process Validation Plan, and/or Installation Qualification Report. - For systems that download firmware to product the BOM showing the firmware requirement shall be provided within the IQR.			
UUT Part Number/Serial Number	Acceptance Criteria	Pass/Fail	Initial & Date
Part Number: 700012243 Serial Number: 22K6P003	The UUT Serial Number is correctly listed at the bottom of the Test Record.	Pass	HZ 02Jul2019
Part Number: 700012245 Serial Number: 22K4B002	The UUT Serial Number is correctly listed at the bottom of the Test Record.	Pass	HZ 04Jul2019
Comments:			
Overall Test Conclusion		Document No.: TE82882-10-IQR Iteration No.: 02 Attachment: 7.5 Page: 1 of 1	
☒ Pass ☐ Fail			

Waters Corporation - Test Record

Part Number: 700012243

Operator: 246154

Serial Number: 22K6P003

Test System: TE82882-10

Test Software: 4.2

Product: 2998 Optics Bench On-Semi

Start Time: 06/13/2019, 10:50:

End Time: 06/13/2019, 15:45:

Order: N/A

Location: Flextronics, SG

TMD: N/A

Firmware: 1.70 Build#: 6363 (Jan 25 2018)

Name	LSL	Measurement	USL	Unit	Outcome
Electrical Safety		True			PASS
Lambda1	178	186.3702	188	nM	PASS
Lambda512	801.5	803.4863	811.5	nM	PASS
Shunt/Cell energy 5ms	80000	118712	250000	counts	PASS
Total Runs	0	19	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	5.08	8	uAu	PASS
Final Drift	-1000	935	1000	uAu	PASS

2998 Optics Bench Final Test Overall Result - PASS

Signed:

246154



Date:

13 JUN 2019

END OF DATA

Document No.:

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Attachment:

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Waters Corporation - Test Record

Part Number: <u>700012245</u>	Product: <u>eLambda Optics Bench On-Semi</u>
Operator: <u>246154</u>	Start Time: <u>07/04/2019, 16:24:</u>
Serial Number: <u>22K4B002</u>	End Time: <u>07/04/2019, 19:37:</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	25.78	40	Degrees C	PASS
Hot Baseline (Audit)	20	26.23	40	Degrees C	PASS
F1 alone (Audit)	20	27.42	40	Degrees C	PASS
F1 and F2 (Audit)	20	25.96	40	Degrees C	PASS
Electrical Safety		True			PASS
Lambda1	178	185.6704	188	nM	PASS
Lambda512	801.5	804.3227	811.5	nM	PASS
Shunt/Cell energy 5ms	80000	80062	250000	counts	PASS
Total Runs	0	10	24		PASS
Noise Runs	0	1	5		PASS
Final Noise	0	4.52	7	uAu	PASS
Final Drift	-1000	885	1000	uAu	PASS

eLambda Optics Bench Final Test Overall Result - PASS

Signed: 246154 	Date: 04 JUL 2019
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END OF DATA

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