

Waters THE SCIENCE OF WHAT'S POSSIBLE.®	EQ Protocol – TB573B QDA Source Enclosure	
Document No: VAL001198	Project number – PVAf111	Version No: 01

Waters - Wilmslow

Equipment Qualification Protocol

TB573B – QDA Source Enclosure

For Internal Use Only

Document reviewed and approved electronically

Author: Edwina Beanland

Date: 05 March 2018

Post Review / Approval

Completion of the following signature blocks indicates your review and approval of the completion of the EQ.

Approved by	Signature	Job Title	Date
Will Hudd	<i>W Hudd</i>	PRODUCT ASSURANCE ENGINEER	04 FEB 2019
Paul Merson	<i>P Merson</i>	PRODUCT ASSURANCE DIRECTOR	14 MAR 2019
* Ashley Jeffrey Martin Cusliffe	<i>MCusliffe</i>	Quality Manager	14-Mar-19

Upon completion of the signature box, the equipment has met all requirements outlined within this document, unless otherwise stated, and is deemed fit for purpose.

* *see*
14-Mar-19

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1. PURPOSE

The purpose of this protocol is to describe the procedures for conducting Equipment Qualification of the Test Box TB573B installed and operated at Venture, Singapore, as detailed in the Equipment Qualification Plan 48867 which has been assessed and deemed that qualification is required as detailed in PVAF 111.

Execution and approval of this protocol will ensure that the equipment is installed and operating to relevant manufacturers specifications, and ensures that the equipment is suitable for its intended use.

The objective of this protocol is to provide documented evidence that:

- The equipment conforms to the relevant manufacturer's technical description and installation requirements.
- The principal features of the equipment and components are installed correctly.
- There is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.
- All equipment calibration requirements have been identified prior to operational testing and performance qualification.
- The equipment operates, as expected, within its required process parameters.

For equipment description and functionality, refer to the EQ Plan 48867.

2. SCOPE

This protocol is restricted to the Test Box TB573B which is to be located in Venture, Singapore.

The list of equipment installation tests are pre-defined within this protocol, however may be omitted if deemed not applicable during execution, by marking as 'N/A' – Not Applicable. Equipment operation/performance testing will be performed as detailed in the EQ Plan and associated PVAF Assessment.

3. RESPONSIBILITIES & SIGNATURE PAGE

3.1. Responsibilities

Prior to start of qualification activities, this document must be pre-approved by completion of the required signature box on the main title page. Refer to the Equipment Qualification procedure 730003703 for details on responsibilities. A Quality Assurance signature is always required, prior to commencement.

3.2. Operator Signature Details

All individuals that require making entries into this protocol after pre-approval are required to fill their details in the table below. This also includes anyone who is tasked with reviewing the document.

Name	Job Title	Signature	Initials
MANOY STEWART	SNR PRODUCT ASSURANCE ENGINEER		MS
WILLIAM HUDD	PRODUCT ASSURANCE ENGINEER		WH

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4. ABBREVIATIONS

Abbreviation	Explanation	Abbreviation	Explanation
CofA	Certificate of Analysis	DQ	Design Qualification
DVM	Digital Volt Meter	EDMS	Electronic Document Management System
EQ	Equipment Qualification	FAT	Factory Acceptance Test
GMP	Good Manufacturing Practices	GDP	Good Documentation Practices
HMI	Human Machine Interface	LED	Light Emitting Diode
PC	Personal Computer	P & ID	Piping and Instrumentation Diagram
PPE	Personal Protective Equipment	PVAF	Process Validation Assessment Form
QA	Quality Assurance	SOP	Standard Operating Procedure
SVAF	Software Validation Assessment Form	URS	User Requirements Specification
VR	Validation Report		

5. REFERENCES

The following references are applicable to completion of this protocol.

Document Number	Document title
48867	Equipment Qualification Plan – TB573 QDA Source Enclosure
48836	TSP – 289008649 QDa ESI Source Enclosure Assembly Bench Test Procedure

6. ACCEPTANCE CRITERIA

Overall acceptance criterion of the equipment is that all the tests are completed and documented satisfactorily with positive outcomes. The equipment must be shown to be fit for its intended purpose.

Each individual acceptance criterion is detailed within the appropriate EQ test sections.

If, during testing and an acceptance criterion is not met, a deviation should be raised as a deviation (section 14) of this protocol. For deviation and concession guidance, refer to the Equipment Qualification Procedure 730003703.

7. DOCUMENTATION

All paper documentation generated as part of the EQ testing should be attached to this protocol by using the attachments section 15. Each attached document should be appropriately labelled with the project number, EQ test number, the protocol number and page number, for example:

PVAF 111 - Test EQ### page # of #

Each page should also be initialled and dated by the operator to comply with GMP/GDP procedures.

Where data is attached to an electronic location, it must be in **.pdf format only** and contain header and footer information with the above EQ reference, if possible. Pages **are not** required to be signed and dated. A copy of the electronic document must be added to the Validation Project Folder:

8. ANCILLIARY EQUIPMENT

Any test equipment used within this EQ protocol as part of testing should be subject to calibration and a planned preventative maintenance program, unless a justification can be provided for use.

All testing equipment should be recorded within each of the EQ test sections and include the asset number, calibration date and frequency of calibration. A copy of each calibration certificate should be attached in section 15 - Attachments,

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following the reference detailed in Section 7 – Documentation. See the Equipment Qualification Procedure for further information on test and calibration equipment.

9. MATERIALS

Any materials/chemicals used in this qualification should be recorded in each of the test sections for traceability and include relevant information such as; certificate of analysis (C of A) lot number, manufactured date, expiry date and number used etc, and be traceable.

10. QUALIFICATION TEST MATRIX

The following installation and operational tests will be performed on TB573B Source Enclosure Test Box. Installation tests are pre-defined and if not appropriate should be entered as N/A during execution of the protocol. Operation testing will test the critical factors outlined in the manufacturers specifications, User Requirement Specification or associated equipment risk assessments detailed within the Validation Plan 48867. Each critical factor should be added to the EQ test matrix (table 1). See the Equipment Qualification Procedure for further information on qualification test matrices and setting up qualification testing.

Table 1 - EQ Test Matrix

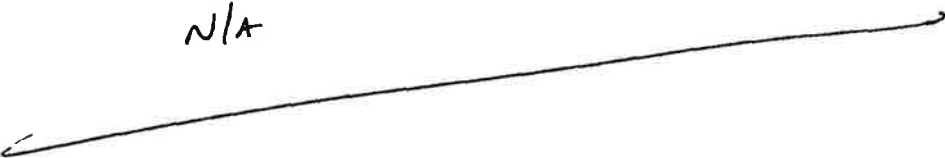
Description of Requirements or Tests	Section
Equipment Details	EQ001
Training Requirements	EQ002
Documentation Review	EQ003
Calibration Check	EQ004
Utility Installation	EQ005
Health and Safety Testing of Equipment	EQ006
Computer Hardware	EQ007
Computer Software	EQ008
Equipment Required for Operational Testing	EQ009
Loss of Power	EQ010
Operator Interface/HMI Testing	EQ011
Source Pressure Test	EQ012
Critical Process Parameter Testing	EQ013

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11. EQUIPMENT INSTALLATION TESTING

11.1. EQ001 – Equipment Details

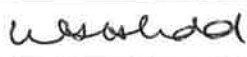
Purpose: To enter equipment details being installed.

Equipment Name	TB573B		
Equipment Description	QDA Source Enclosure Test Box		
Make	N/A		
Model/Type	N/A		
Serial Number	TB573B		
Asset No.	N/A		
Materials of construction	ALUMINIUM, PLASTIC		
Risk Assessment	NONE		
Location	VENTURE GCS LTD, SINGAPORE		
Comments	N/A 		
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)	Wesley	Date	04 FEB 2019

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11.2. EQ002 – Training Requirements

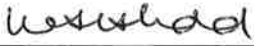
Purpose: To ensure training has been given to relevant personnel, prior to starting qualification work

Internal Training Provided on equipment (if yes give details below)		Yes / <u>No</u>	
External Training Provided on equipment (if yes give details below)		<u>Yes</u> / No	
Comments TRAINING CONDUCTED AT VENTURE, SINGAPORE TO TEST PROCEDURE 48836 V02			
Signed (Operator)			
Reviewed (2 nd Party)			
		Date	10 JAN 2019
		Date	04 FEB 2019

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11.3. EQ003 – Documentation Review

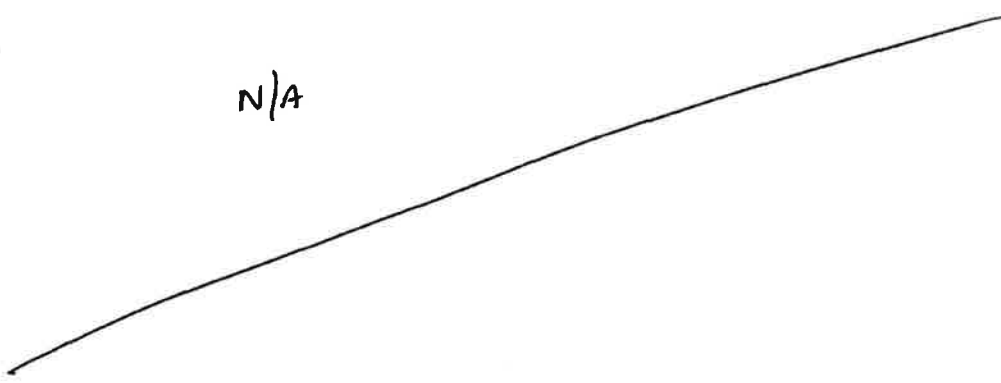
Purpose: To ensure the required documentation to support the equipment is available.

Documentation	Details		Location
Commissioning Documentation	N/A		N/A
Declaration of Conformity (CE certificate)	N/A		N/A
Operation and Maintenance manual	TSP 48836 V2		SAP
Materials List / Spares / Bill of Materials	TB573B - BOM		TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
Drawings	Type	Rev No.	Location
	Electrical Diagram	TB573B-WIRING-DIAGRAM - BHP TB573B-LOCATED-WIRING-DIAGRAM - BHP	TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
	Pneumatic Diagram	N/A	N/A
	Hydraulic Diagram	N/A	N/A
	Mechanical Assembly	TB573B MECHANICAL SPG	TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
	Layout Drawing	TB573BDWG-BHP	TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
	P & ID	TB573B-GH-BHP	TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
	Schematic	TB573B-MAIN-PCB-SCHEMATIC TB573B-CURRENT SENSE - PDF TB573B-DVM-INTERFACE-AD-BMP	TU-ELEC DESIGN > DATE > TEST BOXES > LATEST ISSUE > TB500 - 599
Comments: N/A			
Signed (Operator)			Date 10 JAN 2019
Reviewed (2 nd Party)			Date 04 FEB 2019

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11.4. EQ004 – Equipment Calibration

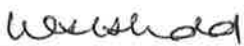
Purpose: To add current calibration state of equipment during qualification

Does equipment under test require calibration prior to EQ activities?		Yes/ <u>No</u>	
Recommended calibration frequency?		Daily/Monthly/Yearly/ <u>Not applicable</u>	
Has Equipment been calibrated prior to starting this protocol? If so, provide details below			
Component/Equipment Details	Calibrated on	N/A	Calibration due N/A
Component/Equipment Details	Calibrated on	N/A	Calibration due N/A
Comments:  N/A			
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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11.5. EQ005 – Utility Installation

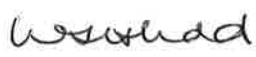
Purpose: To record the utility requirements and connections required for the equipment to operate

Utility	Expected Result	Actual Result	Pass / Fail
Electrical Supply	230v single phase AC socket	AS FOUND AND CORRECT	PASS
Compressed Air Supply	N/A	N/A	N/A
Nitrogen	7 Bar Supply	AS FOUND AND CORRECT	PASS
Exhaust / Vacuum	N/A	N/A	N/A
Water grade	N/A	N/A	N/A
Comments: N/A			
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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11.6. EQ006 – Health and Safety Testing of Equipment

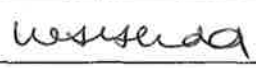
Purpose: To record all Health and Safety details of the equipment and ensure the equipment is safe to use. PPE should be added to the specific test.

Requirement		Result (Yes / No)	Acceptable (Yes / No)
Pressure	Pressure ratings of piping components / pressure vessels are compatible with operating conditions?	YES	YES
	Pressure relief devices provided where applicable?	YES	YES
	Internal lines, regulators and pressure gauges are labelled?	YES	YES
Guarding	Are all mechanical hazards adequately guarded?	YES	YES
	Are all mechanical hazards adequately labelled & identified?	YES	YES
	Are all thermal hazards adequately guarded?	YES	YES
	Are all thermal hazards adequately labelled & identified?	YES	YES
	Are all guards fixed or interlocked?	YES	YES
Exhaust	Equipment exhausted where required?	YES	YES
Pumps	Are facilities services, inputs & outputs, labelled with direction of flow?	N/A	N/A
	Have facilities lines been adequately secured?	N/A	N/A
	Do the pumps and motors have over temperature & over pressure protection?	N/A	N/A
Power Down Test	Does the system returns to a safe state following a power cycle?	YES	YES
PAT Test	Does the equipment require P.A.T. testing prior to use	YES	YES
Flash Test	Does the equipment require Flash testing prior to use	NO	NO
Comments: N/A			
Signed (Operator)			Date 10 JAN 2019
Reviewed (2 nd Party)			Date 04 FEB 2019

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11.7. EQ007 – Computer Hardware

Purpose: Record any computer hardware required for the equipment which has not been supplied by the manufacturer.

Does equipment require computer hardware to operate successfully?		☒ Yes / ☐ No	
If yes, enter details	PC INCLUDING MONITOR, KEYBOARD + MOUSE		
Comments:			
N/A			
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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11.8. EQ008 – Computer Software

Purpose: Record software required for the equipment including operating systems, version numbers, MS Excel spreadsheets any other related software.

Does equipment require computer software to operate successfully?				☒ Yes/ ☐ No	
If yes, enter details below:					
Software Name	Version No.	MS EXCEL 2007	SVAf Approved	☒ Yes/ ☐ No	
Software Name	Version No.	CALGRAFIK Professional 1.1-04	SVAf Approved	☒ Yes/ ☐ No	
Software Name	Version No.	N/A	SVAf Approved	☒ Yes/ ☐ No	
Comments: N/A					
Signed (Operator)				Date	10 JAN 2019
Reviewed (2 nd Party)		Wesley		Date	04 FEB 2019

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12. EQUIPMENT OPERATION AND PERFORMANCE TESTING

12.1. EQ009 – Equipment Required for Operational Testing

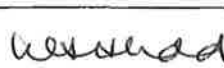
Objective/Rationale: To record any product components/ancillary equipment that will be necessary for operational testing.

Component/Equipment	Requirements	As Found (record item code, lot no, serial no)	Initial and Date
PC	Monitor, mouse serial port	WAT 006730	MS 10 JAN 2019
Dummy ESI Probe	700009641	THREE OF 700009641 PROBES	MS 10 JAN 2019
Test Equipment	TB573	TB573B	MS 10 JAN 2019
Test Equipment	Calibrated Pressure Meter	DPI 705 70530345 ASSET 3125	MS 22 JAN 2019
Test Equipment	Goldbrick Source Enclosure	GB1, GB2 AND GB3	MS 10 JAN 2019
Test Equipment	Calibrated DVM	FLUKE 71 IV SN:35700255	MS 10 JAN 2019
Comments: N/A 			
Signed (Operator):		Date	10 JAN 2019
Reviewed (2nd Party):		Date	04 FEB 2019

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12.2. EQ010 – Loss Of Power

Objective/Rationale: To verify and document the response and recovery of TB573 to a simulated power failure during routine production.

Parameter	Pre-Power Failure		Post Power Failure		Acceptance Criteria Met Y/N Initial and Date
	Expected Result	Actual Result	Expected Result	Actual Result	
TB573 Temperature Reading	Reads Ambient Temperature	CH1 33 CH2 31 CH3 30	Reads Ambient Temperature	CH1 32 CH2 30 CH3 29	YES MS 10 JAN 2019
TB573 Pressure Gauge Reading	Reads 6 Bar +/- 0.5 Bar	5.57 BAR	Reads 6 Bar +/- 0.5 Bar	5.57 BAR	YES MS 10 JAN 2019
TB573 Thermistor LED's	3 LED's Illuminate	ALL 3 LED'S ILLUMINATED	3 LED's Illuminate	ALL 3 LED'S ILLUMINATED	YES MS 10 JAN 2019
CAL3300 Communicates with PC	PC Monitor displays same temperature as TB573	CH1 33 CH2 31 CH3 30	PC Monitor displays same temperature as TB573	CH1 32 CH2 30 CH3 29	YES MS 10 JAN 2019
Were all acceptance criteria met – Y/N					
YES					
Deviation Number (if required)					
N/A					
Comments:					
N/A					
Signed (Operator)				Date	10 JAN 2019
Reviewed (2 nd Party)				Date	04 FEB 2019

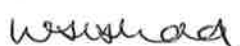
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12.3. EQ011 – Operator Interface/HMI Testing

Objective/Rationale: To verify the sequence of operations for the TB573 test fixtures.

Function	Result Expected	Result Actual	Acceptance Criteria Met Y/N Initial & Date
Fit assemblies to TB573 channel 1, 2 and 3 and turn TB573 on.	Thermistor LED'S illuminate red	ALL 3 THERMISTOR LED'S ILLUMINATED	YES MS 10 JAN 2019
Turn on gas switch to Channel 1	Pressure gauge reads 5.9 to 6.05 bar, LED Channel 1 flow/input pressure illuminates green	6.01 BAR CH1 LED ILLUMINATES GREEN	YES MS 10 JAN 2019
Using the gas regulator reduce the pressure to ≤ 5 bar	LED Channel 1 flow/input pressure illuminates red	PRESSURE REDUCED TO ≤ 5 BAR, LED ILLUMINATES RED	YES MS 10 JAN 2019
Using the gas regulator increase the pressure to 6 bar +/- 0.5 bar. Close exhaust valve	Pressure reading on pressure meter increases	PRESSURE READING INCREASES AS EXPECTED	YES MS 22 JAN 2019
Open exhaust valve	Pressure reading falls to initial value	PRESSURE FALLS TO INITIAL VALUE	YES MS 22 JAN 2019
Close exhaust valve and raise pressure to source to 300mBar	Channel 1 source pressure LED remains green, pressure relief valve activates.	LED REMAINS GREEN AND THE PRESSURE RELIEF VALVE CAN BE HEARD OPENING	YES MS 10 JAN 2019
Turn on gas switch to channel 2	Pressure gauge reads 5.9 to 6.05 bar, LED Channel 2 flow/input pressure illuminates green	6.0 BAR CH2 LED ILLUMINATES GREEN	YES MS 10 JAN 2019
Using the gas regulator reduce the pressure to ≤ 5 bar	LED Channel 2 flow/input pressure illuminates red	PRESSURE REDUCED TO ≤ 5 BAR LED ILLUMINATES RED	YES MS 10 JAN 2019
Using the gas regulator increase the pressure to 6 bar +/- 0.5 bar. Close exhaust valve	Pressure reading on pressure meter increases	PRESSURE READING INCREASES AS EXPECTED	YES MS 22 JAN 2019
Open exhaust valve	Pressure reading falls to initial value	PRESSURE FALLS TO INITIAL VALUE	YES MS 22 JAN 2019
Close exhaust valve and raise pressure to 300mBar	Channel 2 source pressure LED remains green, pressure relief valve activates	LED REMAINS GREEN AND THE PRESSURE RELIEF VALVE CAN BE HEARD OPENING	YES MS 10 JAN 2019
Turn on gas switch to channel 3	Pressure gauge reads 5.9 to 6.05 bar, LED Channel 3 flow/input pressure illuminates green	5.97 BAR LED ILLUMINATES GREEN	YES MS 10 JAN 2019
Using the gas regulator reduce the pressure to ≤ 5 bar	LED Channel 3 flow/input pressure illuminates red	PRESSURE REDUCED TO ≤ 5 BAR, LED ILLUMINATES RED	YES MS 10 JAN 2019
Using the gas regulator increase the pressure to 6 bar +/- 0.5 bar. Close exhaust valve	Pressure reading on pressure meter increases	PRESSURE READING INCREASES AS EXPECTED	YES MS 22 JAN 2019

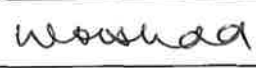
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Open exhaust valve	Pressure reading falls to initial value	PRESSURE FALLS TO INITIAL VALUE	YES MS 22 JAN 2019
Close exhaust valve and raise pressure to source to 300mBar	Channel 3 source pressure LED remains green pressure relief valve activates	LED REMAINS GREEN AND PRESSURE RELIEF VALVE CAN BE HEARD OPENING	YES MS 10 JAN 2019
Turn on Desolvation Heater test switch	CA:3300 reads desolvation heater temperature and stabilises at set point	TEMP SETTLES AT 575C	YES MS 10 JAN 2019
	CAL display on PC monitor displays the same reading at TB573	PC MONITOR READS THE SAME AS TB573	YES MS 10 JAN 2019
Turn off Desolvation heater test switch	Temperature reading on CAL3300 starts to fall	ALL READINGS START TO FALL	YES MS 10 JAN 2019
Were all acceptance criteria met - ☒ Y ☐ N			
Deviation Number (if required)		1	
Comments: DIDN'T HAVE ACCESS TO CALIBRATED PRESSURE METER SO HAD TO GET ONE SENT FROM WILMSLOW. THE SERIAL NUMBERS OF UNITS TESTED WERE LOGGED IN CASE OF FAILURES LATER			
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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12.4. EQ012 – Source Pressure Test

Objective/Rationale: Test to ensure that critical operating requirements are demonstrated to be achievable within defined acceptance criteria.

Critical Requirement	Acceptance Criteria	Actual Value	Acceptance Criteria Met Y/N Initial & Date
Channel 1 – exhaust valve open with gas ON	<10mBar	5.9 mB	YES MS 22 JAN 2019
Channel 1 – Exhaust valve closed with gas ON	>200mBar	263 mB	YES MS 22 JAN 2019
Channel 1 – exhaust valve closed with gas ON but an O ring missing	<200mBar	154 mB	YES MS 22 JAN 2019
Channel 2 – exhaust valve open with gas ON	<10mBar	7.3 mB	YES MS 22 JAN 2019
Channel 2 – Exhaust valve closed with gas ON	>200mBar	242 mB	YES MS 22 JAN 2019
Channel 2 – exhaust valve closed with gas ON but an O ring missing	<200mBar	132 mB	YES MS 22 JAN 2019
Channel 3 – exhaust valve open with gas ON	<10mBar	6.4 mB	YES MS 22 JAN 2019
Channel 3 – Exhaust valve closed with gas ON	>200mBar	270 mB	YES MS 22 JAN 2019
Channel 3 – exhaust valve closed with gas ON but an O ring missing	<200mBar	170 mB	YES MS 22 JAN 2019
Were all acceptance criteria met ☒ Y ☐ N			
Deviation Number (if required)		1	
Comments: n/a			
Signed (Operator)		Date	22 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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12.5. EQ013 – Critical Process Parameter Testing

Objective/Rationale: Test to ensure that operational requirements are demonstrated to be achievable within defined acceptance criteria.

Critical Requirement	Required Settings	Actual Value	Acceptance Criteria Met Y/N
Desolvation heater set point	575°C	575 °C	Y
Desolvation gas flow rate TB573B heater switch on	1200l/hr	N/A	N/A
Heater supply voltage	24v	24.01	Y
Flow measurement pressure	6 bar	6.29v	Y
Were all acceptance criteria met – Y/N Y			
Deviation Number (if required) N/A			
Comments: N/A			
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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12.6. EQ014 - Critical Process Comparison

Objective/Rationale: Test to ensure that operational requirements are demonstrated to be achievable within defined acceptance criteria using the same Source on all three stations (channels).

Test Requirement	Acceptance Criteria Met Y/N Initial & Date
Record the serial number of the Source to be used <u>1311009</u>	YES MS 10 JAN 2019
Run the Source Pressure test as per test specification procedure 48836 on each channel, using the Source with the serial number as above	YES MS 10 JAN 2019
Print out the test record for all three channels and carry out a comparison between the three channels, all three should produce a similar result. Make a pass/fail decision. Append the test records to this protocol.	YES MS 10 JAN 2019
Were all acceptance criteria met ☒ Y ☐ N	
Deviation Number (if required)	
Comments: THE TESTS WERE RUN AND PASSED ON THE 10 JAN 2019. THEY WERE REPEATED AGAIN ON 23 JAN 2019 AFTER THE TESTS USING THE CALIBRATED PRESSURE METER. WILL ALSO REMOTE IN TO CHANGE CAL CONTROLLER PARAMETER ON CH1 DUE TO SOME SET POINT DIFFERENCES	
Signed (Operator) 	Date 10 JAN 2019
Reviewed (2 nd Party) <u>Wesshaad</u>	Date 04 FEB 2019

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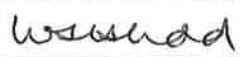
13. MAINTAINING THE VALIDATED STATE

13.1. Planned Preventative Maintenance/Calibration Summary

Purpose: To record the calibration or planned preventative maintenance schedules have been set up as required in the calibration database and provide objective evidence.

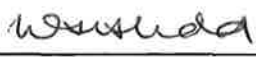
CALIBRATION NOT REQUIRED. HOWEVER THE OPERATORS HAVE BEEN INSTRUCTED TO RUN THE TEST ON THE THREE GOLDBRICK UNITS AVAILABLE PRIOR TO A PRODUCTION RUN

PM DUE FOR 28 MARCH 2019

Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

13.2. Standard Operating Procedure

Purpose: to record the SOP details that must be written for operators to use the equipment.

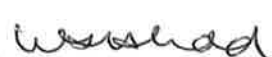
SOP Released in EDMS	☒ Yes No / NA	SOP Number:	488 36
SOP Title	289009649 QDA ESI SOURCE ENCLOSURE ASSEMBLY BENCH TEST PROCEDURE		
Signed (Operator)		Date	10 JAN 2019
Reviewed (2 nd Party)		Date	04 FEB 2019

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14. DEVIATIONS

This section details any deviations raised during execution of this protocol. For deviation guidance, refer to the Equipment Qualification procedure – 730003703.

14.1. Deviation Summary

Deviation No.	EQ Test No.	Details	Closed (Yes/No)	Operator Initial & Date
1	12.3/4	CALIBRATED PRESSURE METER UNAVAILABLE AT TIME OF FIRST TEST	YES	MS 22 JAN 2019
Comments: N/A				
Signed (Operator)			Date	22 JAN 2019
Reviewed (2 nd Party)			Date	04 FEB 2019

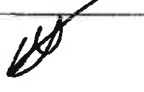
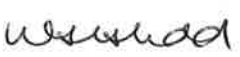


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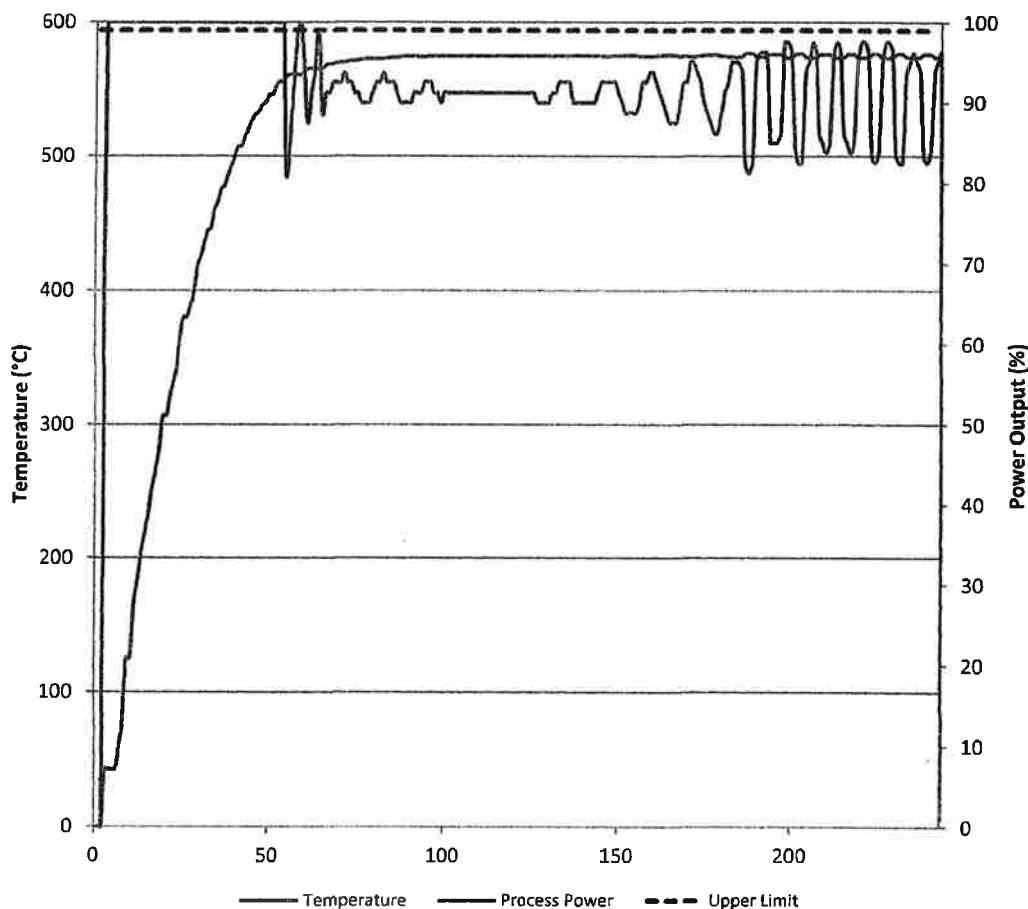
14.2. Validation Deviation Form*

Deviation No.	1	EQ Test No.	12.3 + 12.4
Deviation Details NO CALIBRATED PRESSURE METER AVAILABLE ON 10 JAN 2019 FOR THE INITIAL TEST			
Corrective Actions WILL MUDD SENT METER FROM WILMSLOW			
Outcome TEST WERE CARRIED OUT ON 22 JAN 2019 NO ISSUES WERE FOUND			
Deviation Closed (Yes/No)	YES	Date	22 JAN 2019
Signed (Operator)		Date	22 JAN 2019
Approved (Quality Assurance)		Date	04 FEB 2019

*duplicate as required (single sheet per deviation only)



Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	ALVIN
Assembly Serial No:	131/009-CH1	Test Date:	10 January, 2019



Average Duty cycle after stabilisation

88.12 %

Time taken to reach setpoint

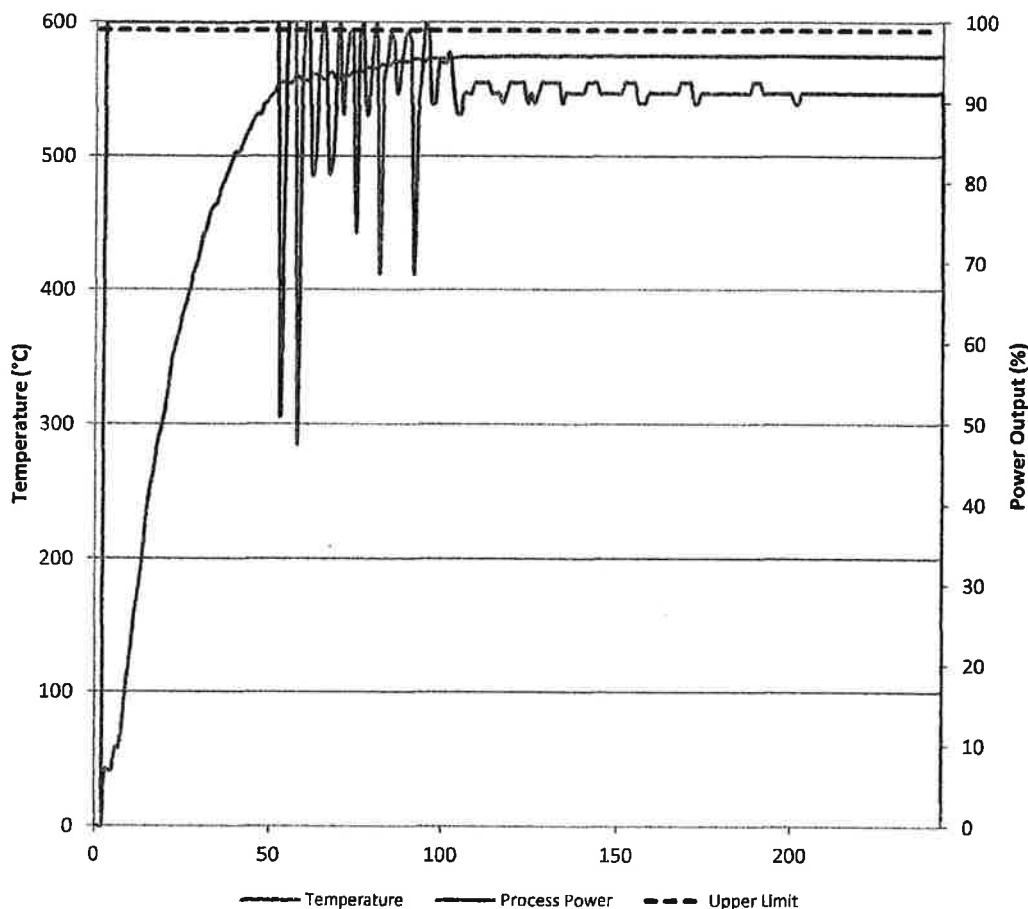
67 Sec

Overall Test Result

PASS

Signature

Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	ALVIN
Assembly Serial No:	131/009-CH2	Test Date:	10 January, 2019



Average Duty cycle after stabilisation

91.28 %

Time taken to reach setpoint

80 Sec

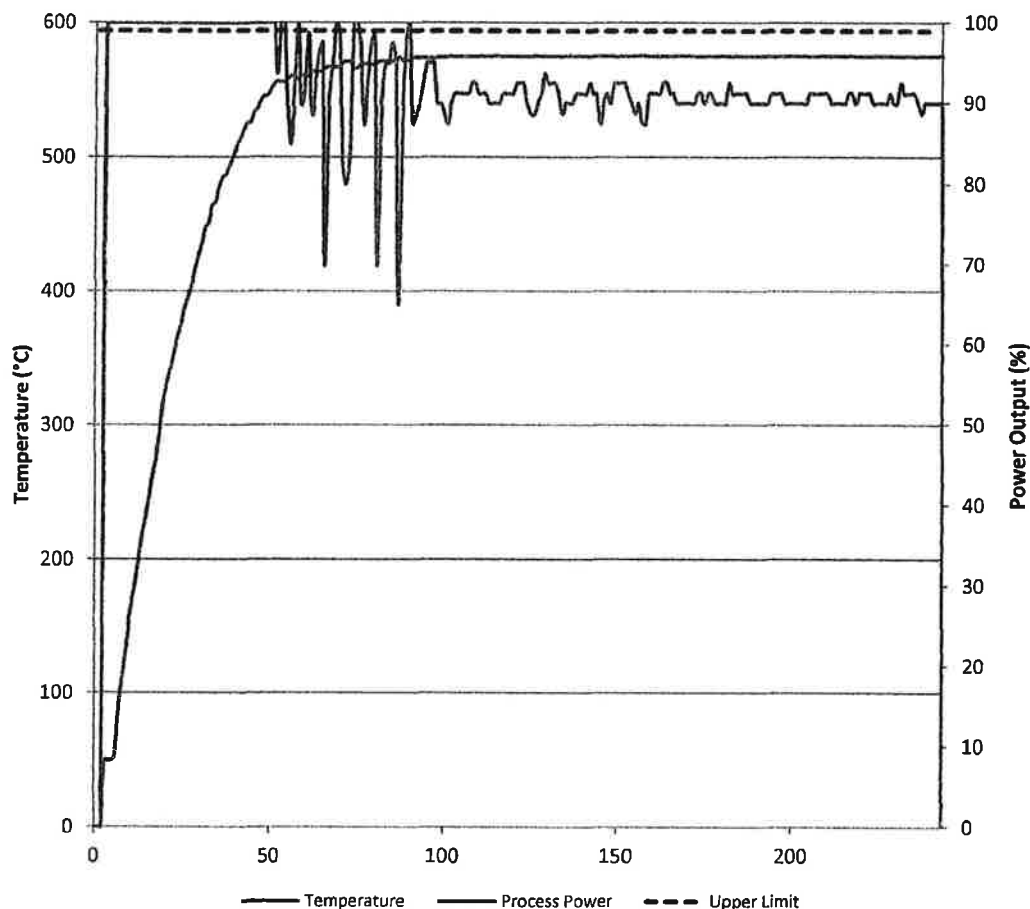
Overall Test Result

PASS

Signature

Doc No: 48872 Version No: 01

Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	ALVIN
Assembly Serial No:	131/009-CH3	Test Date:	10 January, 2019



Average Duty cycle after stabilisation

90.45 %

Time taken to reach setpoint

72 Sec

Overall Test Result

PASS

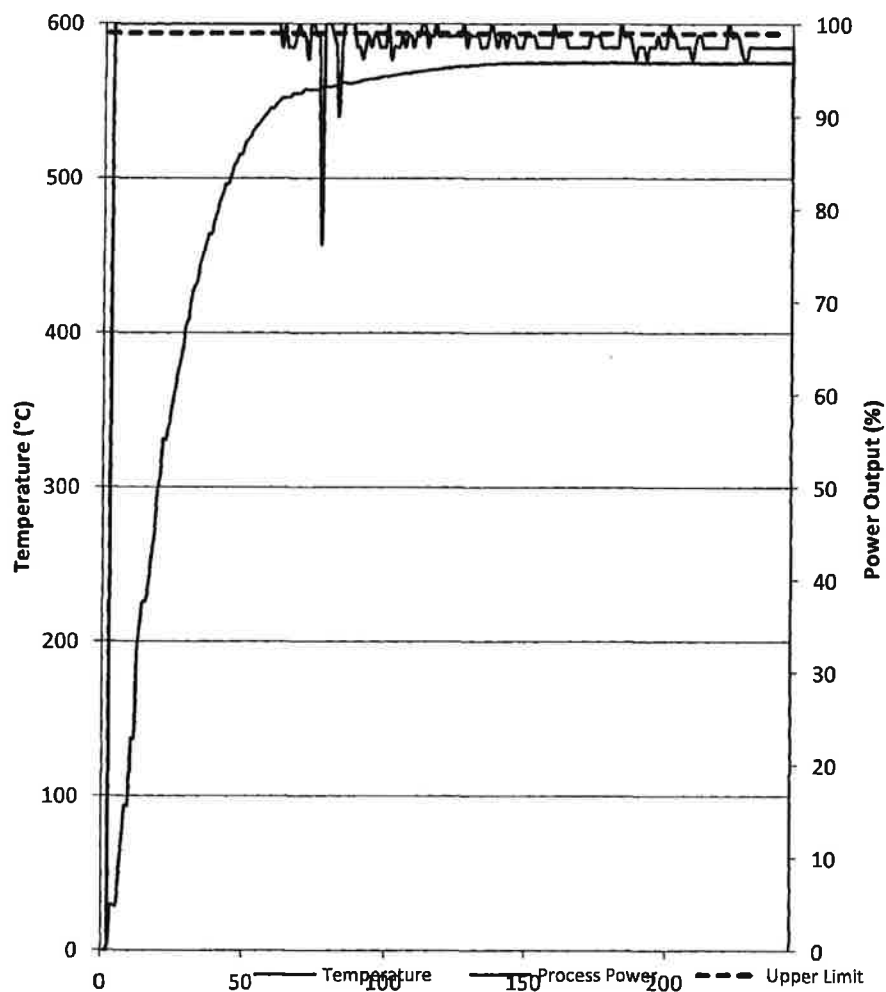
Signature

Doc No: 48872 Version No: 01

Title: **QDa ESI Enclosure
Desolvation heater
test record Sheet**

Page 1 of 1

Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	
Assembly Serial No:	GB1	Test Date:	23 January, 2019



Average Duty cycle after stabilisation

97.67 %

Time taken to reach setpoint

107 Sec

Overall Test Result

PASS

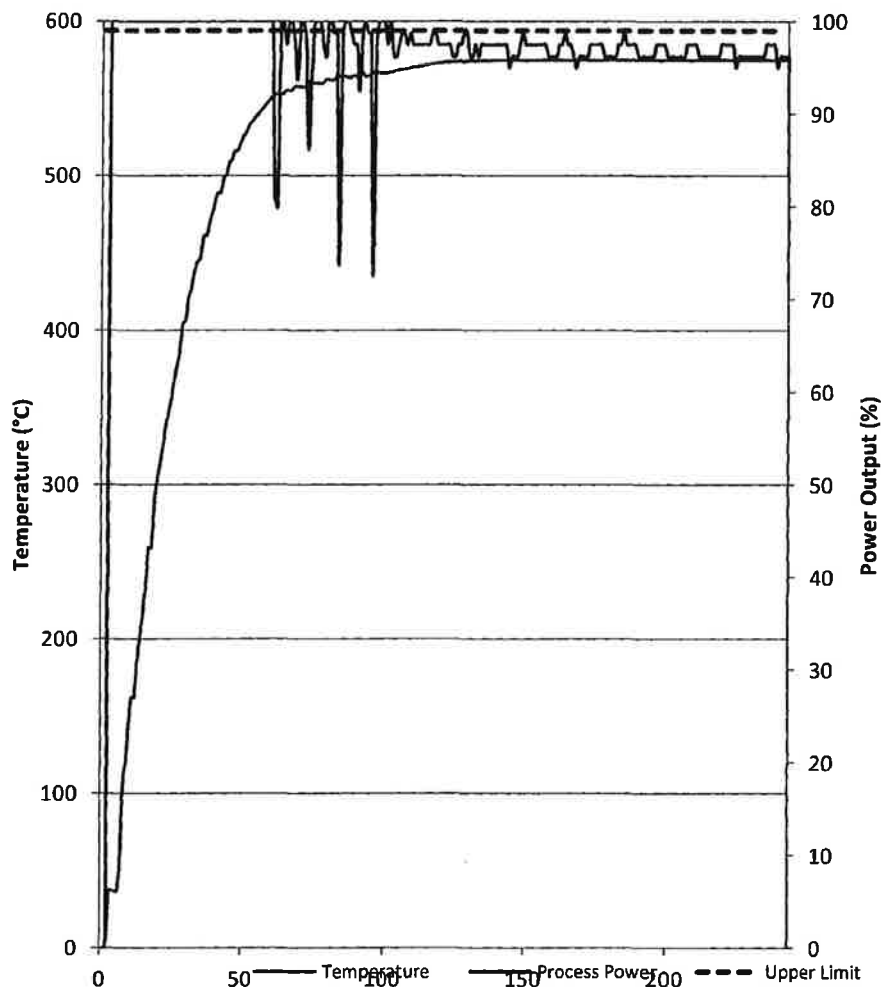
Signature

Doc No: 48872 Version No: 01

Title: **QDa ESI Enclosure
Desolvation heater
test record Sheet**

Page 1 of 1

Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	ALAN
Assembly Serial No:	GB1	Test Date:	23 January, 2019



Average Duty cycle after stabilisation

96.71 %

Time taken to reach setpoint

101 Sec

Overall Test Result

PASS

Signature

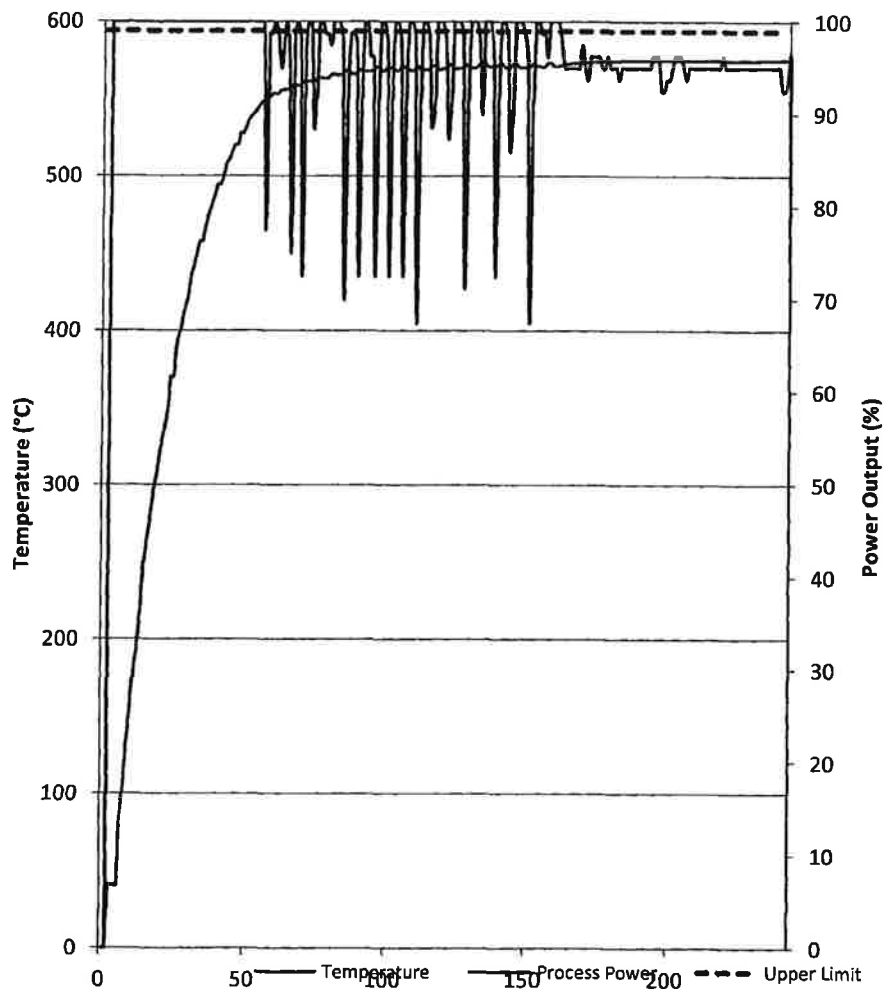
Attachment No 6 E0014

Doc No: 48872 Version No: 01

Title: **QDa ESI Enclosure
Desolvation heater
test record Sheet**

Page 1 of 1

Test Procedure:	48836	Version	2
Heater Serial No.	NA	Resistance	NA
Assembly Part No:	289008649	Tested By:	ALAN
Assembly Serial No:	GB1-CH3	Test Date:	23 January, 2019



Average Duty cycle after stabilisation

94.77 %

Time taken to reach setpoint

103 Sec

Overall Test Result

PASS

Signature

