

Installation Qualification Protocol

Document # 730004135

Version # 03

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Test Script #	IQ-01	IQ Test Name:	Associated Documentation Verification	
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station	
Installation Site: Waters Singapore Contract Manufacturing, CEI 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	PCM II FINAL TEST PROCEDURE 735000887 REV. G		RELEASE GENERAL	
Cal	TE82817 PM PROCEDURE 735002828 REV. A		RELEASE GENERAL	
Comments: 				
Overall Test Conclusion				
☐ Pass ☐ Fail			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	

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Test Script #	IQ -02	IQ Test Name:	Site Verification		
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station		
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore					
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test Execution: - List additional applicable parameters in the Parameters column. Rows may be added as needed. - Using the applicable equipment documentation, define the specification(s) in the Acceptance Criteria column. - Verify and/or measure the applicable parameters and complete the Table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. The reason for why the parameter is not used or applicable shall be explained within the corresponding Installation Qualification Report. Objective Evidence: - Completed IQ-02 Test Script Data Sheet - Photo(s) of the work area, as applicable - The source of each Acceptance Criterion shall be referenced in the IQR if stored in SAP. If not in SAP objective evidence specifying the Acceptance Criterion shall be provided in or as an attachment to the IQR. - Copies of calibration certificates for measurement tools, if applicable					
Parameters	Acceptance Criteria	As Found	Pass/Fail	Initial & Date	
Ambient Temperature	0 °C to 40 °C				
Relative Humidity	20 % to 80 %, Non-Condensing				
Electrical Supply	100 VAC to 240 VAC, 50 Hz/60 Hz ±5%				
Electrical Outlets	Minimum of 4 dedicated outlets				
Network Available	Minimum of 1 dedicated network				
Workspace	The system has sufficient room for the test station, UUT and service				
Test Station Bench	The Test Station Bench is large and strong enough to support the station				
Comments: - Ambient temperature/humidity measured using a Temperature/Humidity Meter - Electrical supply measured using a Multimeter Note: If the electrical supply range or tolerance is not specified for voltage and/or frequency, a tolerance of ±5% may be used in accordance with ANSI C84.1 – Voltage Tolerance Standard.					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					

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Test Script #	IQ-03	IQ Test Name:	Instrumentation Calibration Verification
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore			
Purpose: To verify that all critical instruments are in the calibration database and that a calibration and/or a preventive maintenance has been performed, as appropriate. Test Execution: - List all critical instruments/components and/or sub-systems that require calibration and/or preventive maintenance in the Description column. Rows may be added as needed. - Verify that all listed critical instruments/components have had a preventive maintenance and/or calibration performed in accordance with the PM and/or Calibration procedure(s) or by an outside source, and are listed within the associated calibration database, then complete the table below. Objective Evidence: - Completed IQ-03 Test Script Data Sheet - Copies of calibration and/or maintenance certificates - Screen captures from the associated Calibration database			
Description	Asset #	Cal/PM Dates	Initial & Date
PCM II Final Test Station	TE82817-2	Last Cal/PM: Cal/PM Due:	
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

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Test Script #	IQ-04	IQ Test Name:	Test Software and Instrument Firmware Version		
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station		
Installation Site: Waters Singapore Contract Manufacturing, CEI 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	
Test Equipment Software PCM II	Version: 0.0	Version:			
PCM II Firmware P/N: 361000331	Version: 4.00	Version:			
Comments: Test Equipment Software version specified in 735000887 Rev. G; PCM II Firmware version specified in 361000331 Rev. A					
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____		
☐ Pass ☐ Fail					

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Test Script #	IQ-05	IQ Test Name:	General Safety and Alarms	
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station	
Installation Site: Waters Singapore Contract Manufacturing, CEI Singapore				
Purpose: To verify that the equipment can operate in a safe manner, within its designated location. Test Execution: - List any additional safety related conditions or alarms in the Safety Inspection column, such as: guarding, interlocks, thermal or mechanical safety, chemical, secured gas tanks, restart or power loss, emergency stop, environmental exhaust, electrical safety, noise, safety labels, etc. Rows may be added as needed. EH&S shall be consulted as necessary. - List the associated safety requirement(s)/specification(s) in the Acceptance Criteria column. - Perform an inspection/test of the equipment to assess its safety related conditions, then complete the table below. Objective Evidence: - Completed IQ-05 Test Script Data Sheet - Photo(s) of the secured glass bottles, tanks, etc., if applicable - The source of any applicable Acceptance Criterion shall be summarized in the IQR if stored in SAP. If the source is not stored in SAP, at a minimum the page specifying the applicable Acceptance Criterion shall be provided as an attachment.				
Safety Inspection		Acceptance Criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges		None Found (or mitigated appropriately)		
Glass Bottles		Secure	N/A	N/A
Waste Tanks		Secure and located below the system	N/A	N/A
Emergency Stop		System ceases operation upon depressing the Emergency Stop button	N/A	N/A
Guarding		Shielding in place to prevent hazard during operation		
Comments: Hi-Pot test performed with Safety Analyzer				
Overall Test Conclusion			Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail				

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Test Script #	IQ-06	IQ Test Name:	Functional Verification
Equipment #	TE82817-2	Equipment Name:	PCM II Final Test Station
Installation Site: Waters Singapore Contract Manufacturing, CEI 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: 186003765 Serial Number:		All required CTQ Specification measurements result in a Pass	
		UUT Firmware Version: 4.00	
Comments:			
Overall Test Conclusion		Document No.: _____ Iteration No.: _____ Attachment: _____ Page: ____ of ____	
☐ Pass ☐ Fail			

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Appendix A: TRAINING RECORD

Document #	735000887	Document Title	PCM II Final Test Procedure	Version	06
				Revision	G

Training Performed By:

Printed Name	Signature	Date

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

Printed Name	Signature	Initials	Date

Print multiple copies of this Training Record Template as needed

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TRAINING RECORD

Document #	735002828	Document Title	TE82817 PM PROCEDURE	Version	00
				Revision	A

Training Performed By:

Printed Name	Signature	Date

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

Printed Name	Signature	Initials	Date

Print multiple copies of this Training Record Template as needed

Document No.: _____
Iteration No.: _____
Attachment: _____ Page: ____ of ____