

	DOC. NAME: FINAL FUNCTIONAL TEST STATION INSTALLATION AND OPERATION QUALIFICATION	DOC. No. REV EFFECTIVE PAGE	DAD-PVR-002(#688) A 1 of 8
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Healthcare Technology International Ltd.

DOC NAME: FINAL FUNCTION STATION INSTALLATION
AND OPERATION QUALIFICATION

DOC. No.: DAD-PVR-002(#688)

Rev: A

Revision History of Protocol

Rev.	Description of change	Effective date
A	First issue	

Report No.: _____

Equipment / Fixture No.: _____

Rev: _____ Date: _____

Revision History of Report

Rev.	Description of change	Effective date
A	First issue	

Distributed to: DA,QA,PIE,R&D

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Protocol Approval

Completion of the following signature block signifies the approval of the protocol

Prepared by: _____ Date: _____

Reviewed by:

DEPT.	TITLE	NAME	SIGNATURE	DATE
DA /QA	Manager	Percy Wong		
R&D/ELE	Manager	Stephen Ng		
R&D/Proj. MEC	Manager	Wingo Tang		
PIE	Manager	王文伟		
PROD	Manager	Ben Wong		

Approved by:

RESPONSIBILITY	TITLE	NAME	SIGNATURE	DATE
MGT	DGM	Erik Lee		

Qualification

Completion of the following signature block signifies the protocol has been fully implemented, all the typing data have been double-check with raw data in attached sheets, and the results have been reviewed by and found acceptable

Prepared by: _____ Date: _____

Reviewed by:

DEPT.& TITLE	NAME	SIGNATURE & DATE	The report has been reviewed and meets all acceptance criteria	The report has been reviewed and doesn't meets all acceptance criteria(delete as appropriate)
DA /QA	Percy Wong			Accepted*/Not accepted
R&D/ELE	Stephen Ng			Accepted*/Not accepted
R&D/Proj. MEC	Wingo Tang			Accepted*/Not accepted
PIE	王文伟			Accepted*/Not accepted
PROD	Ben Wong			Accepted*/Not accepted

Approved by:

RESP.& TITLE	NAME	SIGNATURE & DATE	The report has been reviewed and meets all acceptance criteria	The report has been reviewed and doesn't meets all acceptance criteria(delete as appropriate)
MGT	Erik Lee			Accepted*/Not accepted

*-----Accepted as the exceptions have no detrimental effect upon the product.

1.0 Purpose

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The purpose of this installation and operational qualification is to verify that the final function test station (Process code: Q030, Final Functional test station) of HTI-#688 has been installed in accordance with design criteria, engineering specifications, user requirements, and that the system documentation is correct and complete. The purpose of this document is also to verify that equipment operating procedure are suitable to assure consistent operation, and instrument calibrations have been performed.

2.0 Scope

This procedure applies to the installation and operation of Final Function test station (Process code: Q030) of HTI-#688.

3.0 Ref. Document

PFC-688-01: Process Flow Chat
QCI-688-03 QC Final Function Test Instruction
DAD-EVR-000(#688) Equipment Validation Master Plan For
#688(MicroStim)

4.0 Equipment Required

4.1 Final Functional tester

5.0 Equipment description

5.1 The functional tester is used to test the output voltage of device.

6.0 Procedure

6.1 The qualified technician should study carefully the technical documents provided by R&D/DA.

6.2 Connect the power supply cord of the multi-meter into 220V power supply socket.

6.3 Connect the finished goods sample to the functional tester, pay attention to the “+” and “-” polarities, the Red for “+” and the Black for “-”.

6.4 Finished goods test procedure:

6.4.1 Adjust the knob of the voltage meter to maximum position. And press any keys of the sample to begin the testing, the value displayed on the LCD is the Max output voltages of the sample.

6.4.2 Adjust the knob of the voltage meter to minimum position. And press any keys of the sample to begin the testing, the value displayed on the LCD is the Min output voltages of the sample.

6.4.3 Press “RED” or “YELLOW” button on the tester and at the same time press the “P.T.C.” key of the sample, the LED of the sample will display the red or yellow.

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7.0 Product Characteristics

7.1 The sample Max output voltages ≥ 90 V.

7.2 The sample Min output voltages ≤ 20 V .

7.3 The sample supply voltages < 6 V, the LED display red; < 8 V and > 6 V , the LED display yellow; > 8 V, the LED display green;

8.0 Process Parameters and Control Conditions

8.1 Power source: $220 \pm 10\%$ V/AC

9.0 Installation Qualification

9.1 Confirm the necessity of the fixture and its auxiliary has been calibrated by DA engineer and has been stucked with the calibration label, then fill the relevant data in the following sheet:

Fixture/Equipment name	Fixture/Equipment No.	Drawing No.	Calibration Report No:	Duration
Fixture				

Comment:

Performed by: _____ Date: _____

9.2 Confirm the necessity of the supply and the ambient conditions for the operation have been fulfilled, fill the following sheet:

Item	Specified temperature (1)	Mains power(2)	Specified humidity (2)	Actual condition		
				(1)	(2)	(3)
Parameter	20-25°C		60-80%			
Test equipment	Temp & Humidity Meter	Multi-meter				
Calibration No.						

Comment:

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Performed by:_____ Date:_____

9.3 Install the fixture correctly, check and record the materials used. PIE is responsible to confirm the setup correctly as per the requirements established.

Comment:

Installed by:_____ Checked by:_____

9.4 Adjust the tester to reach the following requirements:

9.4.1 Max output voltages

9.4.2 Min output voltages

9.4.3 LED display red

9.4.4 LED display yellow

9.4.5 LED display green

9.4.6 Can the parameters ensure a quality result? If not, DA engineer should instruct the technician to adjust the relative parameters recorded

Comment:

Performed by:_____ Date:_____

Signature: PIE:_____ QA:_____ DA_____

9.5 Prepare the daily and the periodic maintenance record according to the <<Equipment Prevention and Maintenance Procedure>>(HCQSP.9.3).

9.6 Prepare the records of calibration according to the <<Calibration Control Procedure>> (HCQSP11.1).

10.0 Operation Qualification

10.1 Having installed the test station and auxiliary parts, confirm that the IQ requirements have been fulfilled.

10.2 Training the operator on the station. And store the training records in QA dept.

10.3 If the inspector found any deviation in this process, let his Supervisor know and decide how to do. It includes two methods: One is to repair the test station/or debug program control or fixtures; the second is to stop production to solve the problem.

10.4 Conduct the daily and the periodic maintenance by DA according to the

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<<Tester Prevention and Maintenance Procedure>> (HCQSP9.3).

And store the records in DA dept.

10.5 Conduct calibration according to the <<Calibration Control Procedure>> (HCQSP11.1) and store the records in DA dept.

10.6 Conduct 30 pcs #688 samples and 8 know bad boards to confirm the Final functional Test station. Record down all the test parameters of the samples in difference switches positions, fill in the appendix A & B.

11.0 Acceptance criteria for IQ/ OQ

11.1 The necessary documents must be completed.

11.2 Fulfill the requirements mentioned in clause 9.1, 9.2 and 9.3. The tester can be operated freely without any damage and can play all its preset functions consistently.

11.3 The samples performances meet the #688 Test Procedure requirements.

11.4 All the test results of appendix A are failed and all the test results of appendix B are passed

12.0 Conclusion

Signature: PIE:_____QA:_____DA:_____

Dare:_____Date:_____Date:_____

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Appendix A (Know bad board test record) :

Operation verification items

Sample NO.	Failure item	Max	Min	Red	Yellow	Green	Result
1	R8、Q1、R6 open						
2	R7 open						
3	Q2,Q3 bad or open						
4	C5 bad						
5	D3 short						
6	R10 open						
7	T1,T2 bad						
8	Q1 bad or short						

Appendix B (Know good board test record) :

Operation verification items

Sample NO.	Max	Min	Red	Yellow	Green	Result
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

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18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
Pass rate			Reject rate			

Performed by: _____ Date:_____

Signature:PIE: _____ QA:_____ DA:_____