Healthcare Technology International Ltd.

DOC NAME: PCBA FUNCTIONAL TEST STATION
INSTALLATION AND OPERATION
QUALIFICATION

DOC. No.: DAD-PVR-001(#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

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

FORM-0001A

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

The purpose of this installation and operational qualification is to verify that the PCBA functional tester (Process code: Q020, PCBA Functional 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 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 PCBA functional test station (Process code: Q020) of HTI-#688. The scope of this protocol will validate the installation, process procedures, and the ability of the test system to detect the PCBA defects. A quantity of "pass" operator inspected PCBA will be tested by the test system to validate the systems ability to determine response pass/fail.

3.0   Ref. Document

PFC-688-01:   Process Flow Chat
QCI-688-02:   QC Functional Test Instruction
DAD-EVR-000(#688)   Equipment Validation Master Plan For #688 (MicroStim)

4.0 Equipment Required

4.1 PCBA Functional tester.

5.0   Equipment description

5.1 The functional tester is used to read the program of the PCBA's chip.

6.0 Procedure

6.1 The qualified technician should study carefully relevant 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 PCBA test procedure:

6.3.1 Place and fix the PCBA to the tester.

6.3.2 Press the "test" switch to begin the test.

6.6.3 After finished the test, the LCD will display "waiting for testing....". Then push the switch "UP" or "down" to check the test results of last under test device.

7.0 Product Characteristics

7.1 The LED flash with the pulse output.

7.2 Sound generates when the load is about 1KΩ.

7.3 Four class pulses output at the difference modes (T.O.F., D.B.S., P.T.C. and

1Hz)

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 sticked 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℃		60-80%			
Test equipment	Temp & Humidity Meter	Multi-meter				
Calibration No.						

Comment:

Performed by:_____ Date:_____

9.3 Install the fixture correctly, check and record the materials used. DA 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 Push the switch up and down to check 4 modes output results.

    9.4.2 LCD displays the amount and the interval of the pulse.

    9.4.3 Can the switches be adjusted in right positions? Are there clearly label indicated for the positions?

    9.4.4 Can fixture fix the sample firmly in right position for test?

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

Item	Parameter/function	Specification	Inspection method	Result
1	switch locations	Can be pushed up and down		
2	LCD display	displays the amount and the interval of the pulse		
3	fixture	fix the sample firmly		

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 station, 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/QA according to the <<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 sample and 8 know bad boards to confirm the 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 failed and all the test results of appendix B passed bade on the testing specification specified at appendix C.

12.0 Conclusion

Signature: PIE:_____QA:_____DA:_____

Dare:_____Date:_____Date:_____

Appendix A (Know bad board test record):

Operation verification items

Sample No	Failure item	T.O.F. mode width of plus	interval of plus	amount of plus	P/F	D.B.S. mode width of plus	interval of plus	amount of plus	P/F	P.T.C. mode width of plus	interval of plus	amount of plus	P/F	1Hz mode			Result
1	IC pin 17 open																
2	IC pin 8 open																
3	IC pin 9 open																
4	IC pin 10 open																
5	IC pin 11 open																
6	IC pin 12 open																
7	IC pin 13 open																
8	IC pin 8&9 open																

Appendix B(Know good board test record):

Operation verification items

Sample No	T.O.F. mode width of plus	T.O.F. mode interval of plus	T.O.F. mode amount of plus	T.O.F. mode P/F	D.B.S. mode width of plus	D.B.S. mode interval of plus	D.B.S. mode amount of plus	D.B.S. mode P/F	P.T.C. mode width of plus	P.T.C. mode interval of plus	P.T.C. mode amount of plus	P.T.C. mode P/F	1Hz mode	Result
1														
2														
3														
4														
5														
6														
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Performed by: _____ Date: _____

Signature:PIE: _____ Q A: _____ DA: _____

Appendix C: Testing specification

T.O.F. mode			D.B.S. mode			P.T.C. mode			1 Hz mode		
Width of plus	Interval of plus	Sum of plus									
200NS	2N2	4									