



# **n Bioamp Test Fixture Validation Test Plan**

990-03848-00  
Rev 1

Bioamp Test Fixture Validation Test Plan  
Amber Bioamp Test Fixture and Peripherals

Version 0.0.1 (DRAFT)



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## 1 Purpose

Describe the Validation Test Plan for the EEG Bioamp Test Fixture including the Test Laptop with Test Tool Software, Barcode Reader, and Bioamp as required. This includes verification of the Test Fixture to ensure ability to test the Bioamp DUT with predefined configurations and ensure capture of all test results and configuration. As a result of the validation test, the Test Fixture will be verified in working condition to accurately test Bioamp DUT's.

The objectives of the Bioamp Test Fixture Validation Test Plan are to:

- 1) Ensure the Bioamp Test Fixture is in working condition and provides accurate results as configured.
- 2) Ensure the Bioamp test method is repeatable and reproducible using a given test fixture.
- 3) Ensure the Bioamp results are accurate using a given test fixture.
- 4) Generate a summary and detailed report for Tests executed.
- 5) Create Log and CSV outputs to show successful execution of Test Fixture Validation Tests.

The following tasks are defined in the Bioamp Test Fixture Validation Test Plan:

- 1) Execute various Validation Test approaches for Bioamp Test Fixture(s).
- 2) Analyze data using appropriate statistical methods to determine accuracy and precision of the test method.
- 3) Capture Log and CSV Tests and complete corresponding Summary and Detailed Reports for results.
- 4) Complete Test Protocol Script to ensure accurate testing of test steps.
- 5) Enter issues identified in Buganizer and assign to appropriate lead for resolution.
- 6) Identify pre and post test execution requirements.
- 7) Identify environment set up requirements.
- 8) Identify scope of test execution.

## 2 Scope

2.1 This document shall include the following features to be tested:

- 2.1.1 All components required for validation testing of EEG Bioamp Test Fixture.
- 2.1.2 Test steps for the Test Fixtures validation testing.
- 2.1.3 Verification of Test Fixtures Hardware and results.



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2.1.4 Amplitude and Frequency tolerances verification based on configuration.

2.1.5 Collection of Test results

2.1.6 Analysis and reporting of Test Results

## 2.2 Out of Scope

2.2.1 Performance test related to time of sending signals and receiving results from DUT.

2.2.2 Power level measurements to measure fluctuations in power to DUT.

2.2.3 Firmware validation.

2.2.4 Stress testing of Test Fixtures.

2.2.5 Error Handling and alerts for Test Tool Software.

2.2.6 Test Laptop system setup.

## 3 Responsibilities

### 3.1 Technical Program Manager

3.1.1 Overall approval / signoff of completed test validations, results (including issues identified) with oversight into complete system including Test Fixtures and components.

### 3.2 Project Lead

3.2.1 Provides initial component approval / signoff of completed test validations and scripts, results (including issues identified).

### 3.3 Technical Lead (Hardware)

3.3.1 Responsible for execution of the Test Fixture tests and components and software utilization. Provides validation of software based on requirements. Logs issues encountered. Provide signoff of completed validation tests and scripts as well as results including entering of issues identified.

## 4 Definitions and Abbreviations

Acronym/Term	Definition
EEG	Electroencephalography
Session	One or more contiguous tasks for a single user/participant
SDLC	Software Development Life Cycle
SOP	Standard Operating Procedure
Task	Individual stimulus test
Repeatability	The variance of a measurement taken by a single person on the same DUT under the same operating conditions.



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Reproducibility	The variance introduced when different operators or instruments measure the same device
Gauge R&R	A method used to analyze the variability of a measurement system using ANOVA, with the goal to differentiate the source of variability to either the DUT or the measurement system. This primarily addresses the <u>precision</u> of a measurement system.

## 5 References

### 5.1 Applicable Standards

This procedure demonstrates compliance to the requirements of the following Standards and Regulations:

Document Number	Title
21 CFR Part 820.250	Statistical Techniques
21 CFR Part 820.72	Inspection, Measuring and Test Equipment

### 5.2 Internal Documents

The following documents are necessary parts of this procedure. In the event of conflict, this document supersedes:

Document Number	Title
990-03830-00	Software Installation, Verification and Validation
990-03841-00	Amber Test Fixture and Software Test Tool Requirements Specification
990-03850-00	Test Form LHR: Bioamp Test Fixture - R&R Test
990-03849-00	Test Form LHR: Test Fixture - Software Test Tool Accuracy Test
990-03842-00	Amber Bioamp Test Fixture and Software Test Tool V&V Test Script



## 6 Test Fixture Summary Overview

The Amber EEG Bioamp Test Fixture

### 6.1 Bioamplifier Test fixture

Utilized for testing of the Bioamplifier.

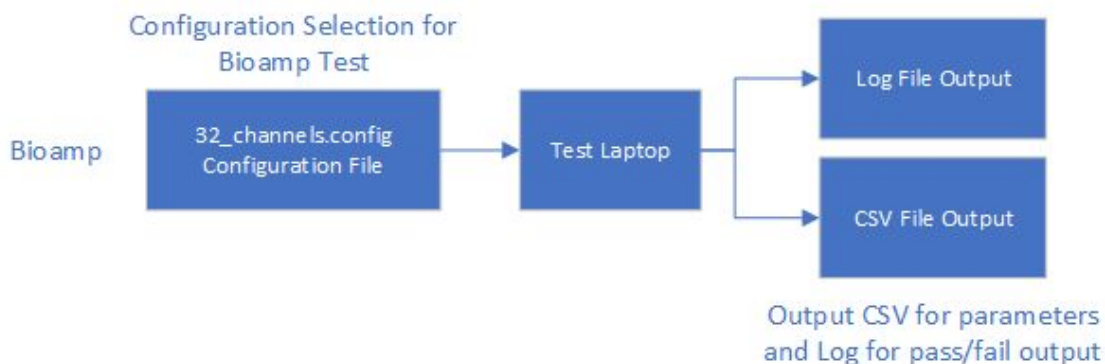
Fig 1.



### 6.2 Hardware Testing - Linux Laptop w/ Software Test Tool

Includes the Linux Laptop and Software Test Tool for initiating the Bioamp Test and reading the DUT results.

Fig 2.



### 6.3 Barcode Scanner

Includes the Barcode scanner utilized for reading the unique DUT barcode and initiating the channel test sequence.



Fig 3.

Barcode Reader reads DUT  
barcode



## 7 Testing Strategy

### 7.1 Actors/Roles

Actor	Role
Quality Assurance Tester / Operator	Responsible for configuring and setup of the Test Fixture tests. Executes the tests. Logs the test results in the report and manages all test equipment.
Test Team	All Test actors who will assist with the testing effort.
Quality Assurance Test Reviewer	Signs of on the Quality Assurance Tester test results (second approver)

### 7.2 Recording of Test Results

#### 7.2.1 Logging

##### 7.2.1.1 Test Log file

Copied for each test executed to the “Logs” folder located on the desktop of the Test Laptop as [x].log files.

- Test Logs include test parameters and additional errors encountered.





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- Barcode, test results, Software Test Tool version, and the DUT settings (e.g. Firmware version)
- Logfile naming convention: <barcode id><timestamp>.LOG format

### **7.2.1.2 Test Data file**

Copied for each test executed to the “Logs” folder located on the desktop of the Test Laptop as [x].csv files.

- Test data includes test results from the individual tests executed.
- Test data naming convention: <barcode id><timestamp>.CSV format

### **7.2.1.3 Test Log data specification**

- Date Time of execution
- Configuration File name
- Parameters executed
- Bioamp Port
- Bioamp Serial Number
- Firmware Version
- HW Version
- Bioamp Version - FW Version
- Bioamp Version - HW Version
- Channel # ON/OFF
- Channel # Gain setting
- Recording length
- Recording samples
- Summary
  - a) Channel | amp | exp.amp | freq | exp.freq | PASS / FAIL
  - b) All Channels PASSED or FAILED
- Log file location and name
- CSV file location and name

### **7.2.2 Reporting**

Each study will require the collection of test results and test execution reporting data for tracking of test execution and results. These elements will be collected in associated report outputs.

#### **7.2.2.1 Bioamp Test Fixture Validation Test Reports**

- Summary results for test execution - see Validation Summary Report



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- Report for testing Reproducibility and Repeatability (R&R) results captured.
- Report for testing Accuracy results captured.
- Test Protocol Script for successful execution of test steps.

### **7.2.2.2 Bioamp Test Fixture Validation - Software Test Tool output**

- Detailed summary results and interpretation for test execution that are provided in the LOG files.
- Detailed raw data results for the test execution that are provided in the CSV files.

### **7.2.2.3 Test Details**

#### **7.2.2.3.1 Test Protocol Script details**

- Ensure each test procedure step was completed successfully as required.
- Ensure the R&R Summary Log included was completed with all needed test steps.
- Each test report will have 4 signature approvers.
  - a) Quality Assurance Tester (Operator 1) who executed the Test 1
  - b) Quality Assurance Tester (Operator 2) who executed the Test 2
  - c) Quality Assurance Tester (Operator 3) who executed the Test 3
  - d) Quality Assurance Reviewer of the Testers test results.

#### **7.2.2.3.2 Bioamp Test Fixture Validation Report details**

- Date/Time of Test
  - a) Time test was initiated
- Test Equipment: SW Version
  - a) SW version for Software Test Tool
- Test Equipment: HW Part # (REF)
  - a) Part # for the Bioamp Test Fixture
- Test Equipment: HW Serial #
  - a) Serial # for the test fixture being tested
- Test Procedure: Document
  - a) Validation test document used for the test script executed.
- Test Procedure: Revision
  - a) Revision for the Validation test document - test script executed.

For each test



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- Test ID
  - a) Unique identifier for the test - each test will be given a unique number to identify the test executed
- Bioamplifier (DUT): Firmware Version
  - a) Bioamp DUT firmware version
- Bioamplifier (DUT): HW Part # (REF)
  - a) Bioamp DUT HW Part #
- Bioamplifier (DUT): HW Serial #
  - a) Bioamp DUT HW Serial #
- Test Results: Channel Test Results (PASS/FAIL)
  - a) Test results for the channels. PASS only if all PASS.
- Test Results: Overall Test Results (PASS/FAIL)
  - a) Test results for the test plan steps. PASS only if all PASS.
- Test Results: Test Result .CSV file
  - a) CSV file location for the produced test file
- Test Results: Test Result .LOG file
  - a) LOG file location for the produced test file
- Test Results: Issues Desc
  - a) Description of Issues encountered during the testing. This includes execution functionality

### **7.2.2.3.3 Bioamp Test Fixture Validation Detail Report - LOG File details**

- Channel [#]
  - a) 1-32 channels
- Amp
  - a) Amplitude collected
- Exp.Amp
  - a) Expected Amplitude from configuration
- Freq
  - a) Frequency collected
- Exp.Freq
  - a) Expected Frequency from configuration
- Pass/Fail
  - a) PASS or FAIL



### **7.3 Validation Summary Report**

The Test Protocol Script will serve as the validation summary report and will be completed based on recorded test results. The PASS/FAIL for the Test Fixture(s) will include testing of requirements including evidence of installation in the testing environment and performance metrics collected from test execution.

The following documents will be utilized for the generation of the Validation Summary Report (Test Protocol Script):

- Bioamp Test Fixture Validation Reports
  - Repeatability and Reproducibility Report
  - Accuracy Report
- Bioamp Test Fixture Validation Details
- 

### **7.4 System and Integration Testing**

#### **7.4.1 Definition**

The Bioamp Test Fixture serves as a source for simulating through an integrated connection with the Bioamp adapter and provides input to test a Bioamp component. The Bioamp connects to a Test System and executes a test Software that sends and receives test data and generates output logs.

#### **7.4.2 Participation**

The Quality Assurance Tester / Operator will perform the System and Integration Testing.

#### **7.4.3 Methodology**

- The Test Team sets up a space that allows appropriate testing of the Bioamp Test Fixture
- The Test Team sets up and configures the Software Test Tool.
- The Test Team sets up the hardware components and connects to the Software Test Tool.
- The Test Team executes the Test script.
- The Test Team will log completed integrations and setup.
  - Issues identified during the setup and configuration steps will be logged in the Buganizer issue tracking system for resolution.



- If applicable, the Software Test Tool Log data will be reviewed for additional issues encountered.
- The Test Team will assess all components integrated successfully.

## **7.5 Performance and Stress Testing**

### **7.5.1 Definition**

The Bioamp Test Fixture requires the capability of sending reliable test data to a Bioamp to verify the device function without inaccuracy or unacceptable variation in performance.

### **7.5.2 Participation**

The Quality Assurance Tester / Operator will perform the Performance and Stress Testing.

### **7.5.3 Methodology**

- The Quality Assurance Tester / Operator will execute multiple Tasks.
- Each test executed will be monitored for performance related to one or more of the following:
  - Accuracy in response
  - Consistency in performance.
  - Consistency in results
  - Consistency in execution
- Results for tests performed will be logged by the Quality Assurance Tester / Operator.
- If applicable, the Software Test Tool Log data will be reviewed for additional measurements recorded.

## **7.6 Failure Mitigation**

Test Failures recorded will be re-tested for accuracy to duplicate the Failure if outside the acceptable failure rate.

If a Test Failure requires software modification:

- Test Fixture related Failures outside determined acceptable rates will require retest to ensure reliability, reproducibility, and accuracy.

All retests will be logged for future reference in the Buganizer system.



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## 7.7 Deliverables

Test Summary Report: Summary report of test overview and results for each test conducted.

- Repeatability and Reproducibility Test Report(s)
  - Validation of amplitude and frequency for utilized channels.
  - Gauge R&R for channel results.
- Accuracy Test Report(s)
- Buganizer log of issues.
- Log File and CSV files for each Test executed.

## 7.8 Acceptance Criteria

In order to be considered compliant, tests executed will be evaluated independently for acceptance related to the type of test being conducted.

### 7.8.1 Reliability and Readability Test Acceptance Criteria

- Overall PASS/FAIL of all channels tested will be used for acceptance.
- Gauge R&R will be calculated using statistics software, such as JMP or equivalent.  
Industry standard acceptance criteria is as follows:

Status	% Gauge R&R	% Contribution
Acceptable	<10%	<1%
Marginally Acceptable	10%-30%	1%-9%
Unacceptable	>30%	>9%

- All categories (amplitude and frequency for each channel tested) must fall within acceptable range for Gauge R&R for the precision of the test to be considered validated.

### 7.8.2 Accuracy Test Acceptance Criteria

- Overall PASS/FAIL of all channels tested will be used for acceptance.

### 7.8.3 Validation Test Protocol Script Criteria

- Overall PASS/FAIL of Test Protocol execution tested based on test steps will be used for acceptance.



## **7.9 Schedule**

Prior to release to a site, each Test Fixture will be scheduled for execution of 2 test categories.

### **7.9.1 Bioamp Repeatability and Reproducibility (R&R) Tests**

#### **7.9.1.1 Process**

- 3 Operators will execute the test method for each of 10 Bioamp DUT's replicated 3 times with Bioamp DUT's randomly selected in order of test execution for a total of 90 tests (30 tests per Operator).

#### **7.9.1.2 Results**

- Results reported will be analyzed for results of channels available.
- Results reported will be analyzed for Gauge R&R statistical analysis utilizing channel and associated attribute.

### **7.9.2 Bioamp Accuracy Tests**

#### **7.9.2.1 Process**

- 1 Operator will execute the test method and complete the test form. The operator will first generate output failure results using a configured hardware signal generator. These results are loaded onto the Software Test Tool - Laptop. A command line execution is initiated to prompt for executing a Software Test Tool accuracy test for each of 32 channels for the appropriate amplitude and frequency. Test results are output to the LOG file and results with expected PASS or FAIL recorded in the Accuracy Test Form.

#### **7.9.2.2 Results**

- Evaluate results for consistency in output of results for each of 32 channels for each test performed to ensure results are consistent and PASS / FAIL accurately for tolerances.

## **7.10 Tools**

7.10.1 Buganizer will be utilized for tracking of issues identified.

7.10.2 Statistical analysis software, such as JMP, will be used to analyze results.



## **7.11 Issue Resolution**

7.11.1 Upon completion of the testing of the Test Fixture, issues identified will be logged in each report maintained for the Test Fixture.

7.11.2 Identified issues will be entered into the Buganizer software.

7.11.3 Each issue will be assigned to the appropriate development team member for resolution.

- Issues identified will be reviewed.
- Each issue will be prioritized for resolution if determined for resolution.
- Each issue will be assigned an estimated resolution date if determined for resolution.

7.11.4 If scheduled for resolution,

- Issues are resolved.
- Upon completion of all issue resolution, the DUT is scheduled for retesting.
- Buganizer software is updated with status

7.11.5 If not scheduled for resolution,

- Buganizer software is updated with status

## **7.12 Risks / Assumptions**

7.12.1 Assume EEG Bioamp DUT's are in working condition prior to validating the Bioamp Test Fixture.

7.12.2 Assume Barcode Scanner meets requirements for reading the DUT Barcode format

7.12.3 Assume the Barcode Scanner is functional and working properly.

7.12.4 Assume the Software Test Tool is preconfigured with credentials for authorized log in user.

## **8 Environment Requirements**

### **8.1 Bioamp Test Fixture**

8.1.1 Bioamp device under test (DUT)

10 separate Bioamp DUTs for testing





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### 8.1.2 32-Channel Bioamp Test Fixture

1 Bioamp Test Fixture

## 8.2 Hardware Testing - Linux Laptop w/ Software Test Tool

1 Linux Laptop with pre-installed and configured Software Test Tool

### 8.2.1 Software Specification

Operating System Software	Linux DebianStretch 9.8
Additional Installed Packages	Python 2.7.3 Python libraries: pyserial v3.4 numpy v1.16.0 Scipy v 1.2
USB Port software	FTDI Driver USB Serial driver supported on Linux USB HID device driver support

### 8.2.2 Hardware Specification

CPU	Intel Core i5-8400H or greater
RAM	8GB+
Storage	100GB (HDD or SDD)
Monitor	15"+ (1x15x10)
Battery	56 WHr+
Communications Port (DUT)	USB 2.0 Port Type A
External Barcode Scanner Port	USB 2.0 Port Type A
External Thumbdrive Port	USB 2.0 Port Type A
Weight	<4lbs



## 8.3 Barcode Scanner

### 8.3.1 Hardware Specification

OS	Linux compatible
Communication Port	USB 2.0 Type A OR Bluetooth Wireless enabled (via USB 2.0 Type A fob)
Barcode Format	2D barcode format
Other Features	Sound for scan Configurable Instant Upload Scanning Trigger Key Scanning

## 8.4 Accuracy Testing - Signal Generator Test Fixture

8Hz, 250  $\mu$ V Signal Generator Test Fixture

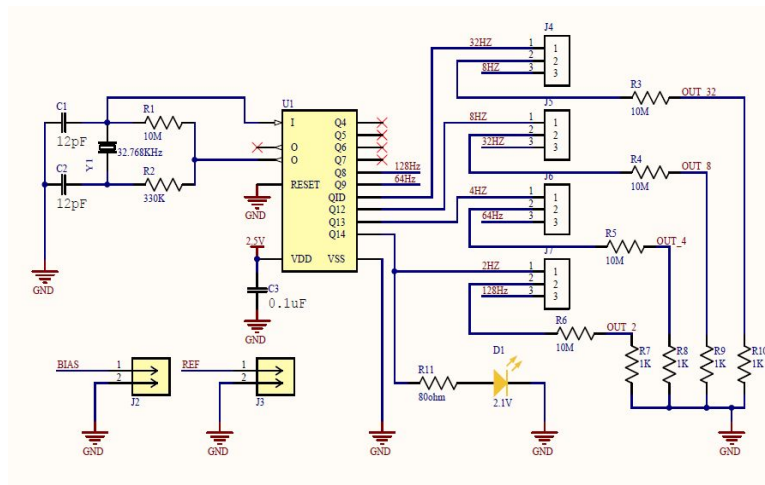
4Hz, 107  $\mu$ V Signal Generator Test Fixture

4Hz, 250  $\mu$ V Signal Generator Test Fixture

### 8.4.1 Calibration

Utilize a crystal controlled oscillator to output a signal of known amplitude and frequency that is measurable (millivolt range) with calibrated test equipment. [see Fig 4].

Fig 4.





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This known signal source will be fed into a voltage divider that will convert the amplitude to the desired values to be used to validate the software (approximately 200 microvolts). The equation used to set the voltage divider is based on Ohm's law where  $(r2/(r1+r2))V_{source} = V_{out}$ .  $V_s$  is in the volts range and  $V_{out}$  is in the microvolts range. Precision resistors are used in the divider circuit.

### 9 Approvals

The Validation Test Protocol Script, Validation Summary Report and Sub Reports require signature approval from the Product Owner (or Project Lead), Technical Program Manager and/or Test Lead(s). The installation summary report will be approved by per 990-03831-00, INSTALLATION AND QUALIFICATION.

### 10 Revision History

Revision History		
Rev	Description Of Change	Effective Date
1	Initial Release	5/29/2019
2	Test Fixture - Accuracy Test specification	7/16/2019