



IEC 60601-1:2006+A1:2013

TEST REPORT

For

X Development, LLC.

100 Mayfield Ave. Mountain View, CA 94043, USA

Model: X

Report Type: Original Report		Product Type: Medical Device	
Report Number:	R1909123-60	0601	
Report Date:	2019-09-13		
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* This report may contain data that are not covered by the A2LA accreditation and are marked with an asterisk "*" and a sterisk "**

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1 General Information for Equipment Under Test (EUT)

Test item description :	A Bioamplifier		
Trademark:	Waived for final IEC 60601-1:2015 evaluation intended for actual production		
Manufacturer:	X Development		
Model and/or type	Model: X		
reference:	Reference: 710-03064-01		
Serial Number(s):	B19080107		
Rating(s):	120V/60Hz	A	

1.1 Product Description:

This test and measurement report was prepared on behalf of *X Development LLC*. for the company's product *Model X* which will henceforth be referred to as the EUT (Equipment Under Test). The EUT is an electrophysiological device used to amplify the signal integrity of physiologic electrical activity gathered by the connected headset and output the amplified signals for recording.

Labelling Information

Copy of marking plate and labels and summary of test results (information/comments):



1.2 EUT Configuration Details

Manufacturer	Description	Model	Serial Number(s)
X Development	A Bioamplifier	X	B19080107

1.3 Summary of Testing and Results

The following tests were performed at BACL on the Bioamplifier, Model X:

- 1) Impact Test
- 2) Drop Test

1.4 Safety Test Equipment

Description	Model No.	Manufacturer	BACL ID	Serial No.	Calibration Due Date
Impact Test Ball	1TB-01	ED&D	00824	00824	2020-10-31
Drop Test Floor	N/A	BACL	01031	N/A	N/A

1.5 Results

15.3	TABLE: Mechanical S	LE: Mechanical Strength Tests			
CLAUSE	NAME OF TEST	Test conditions	Observed results/Remarks		
15.3.3	Impact Test	The unit was placed on a solid supporting surface with the surface that was impacted positioned horizontally. One impact was imparted to the surface by a smooth steel sphere 50mm (2 in.) in diameter and weighing .05kg (1-3/16lbs.). The sphere was allowed to fall freely through a distance of 1.3m (51-3/16 in.). This was done on both the top and bottom of the device.	There was no damage or hazards to the EUT following the test.		
15.3.4.2	Drop Test (for portable ME equipment)	The EUT was lifted to a height of 1m. A 50mm thick hardwood board was laid flat on a hard floor. The sample was then dropped on the top, bottom, front and side.	No damage or hazards to t following the test.	he EUT	

2 EUT Photographs

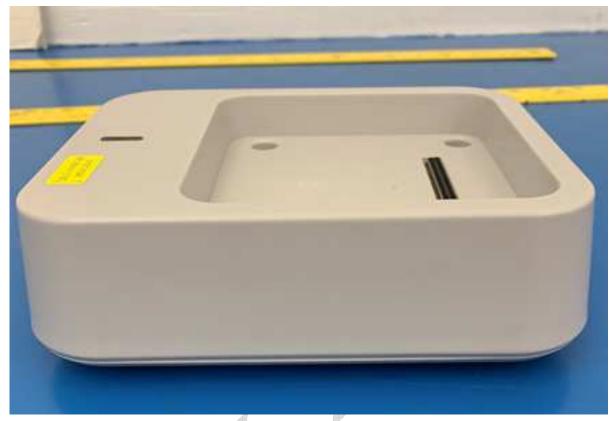
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2.2 EUT- Overall Bottom View



2.3 EUT- Overall Right Side View





2.4 EUT- Overall Left Side View





2.5 EUT- Overall Front Side View





2.6 EUT- Overall Backside Side View



---END OF REPORT---