



# Non-conformance Form

990-03826-00

Rev 1

Revision History		
Rev	Description Of Change	Effective Date
1	Initial Release	6/14/2019

<b>Initiator:</b> Zoey Zweber	<b>Date:</b> 6/14/2019	<b>NCR Log #:</b> NA
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Nonconformance Identification	
<p><b>Description of Nonconformance:</b></p> <p>According to G5218 690-14180-01_01 INSPECTION REPORT, the connector alignment fixture has multiple out of spec dimensions according to the engineering drawing. This inspection was a full FAI of the assembled part.</p> <p>Part Number: 690-14180-01 Description: MECH, FIXTURE, CONNECTOR ALIGNMENT, AMBER Serial Number: AF19030602</p>	
Does Non-conformance Impact Product? <i>(check one)</i>	
<p><b>YES</b> _____</p> <p>Conduct a Risk Analysis</p>	<p><b>NO</b> <u>X</u> _____</p> <p>Determine if Systemic Issue</p>



Risk Management File Reference	
<b>Document Title:</b> N/A	<b>File location reference:</b> N/A
<b>DMR Reference:</b> N/A	<b>DHR Reference:</b> N/A


Results of Risk Analysis
NA

Non-conformance Disposition (check one)					
<b>CAPA</b> (non-products only) _____	<b>Use As Is</b> ____ <u>X</u> ____	<b>Rework</b> _____	<b>Return to Supplier</b> _____	<b>Lab Use Only</b> _____	<b>Scrap</b> _____
<b>Rationale:</b> The tool still functions as intended, to align the connector on the PCBA within the bioamp enclosure. Tool was tested with many production enclosure parts and no fit issues were realized. Non-conformances are not expected to impact assembly nor finished product quality.					

<b>Dispositioned by:</b> Zoey Zweber	<b>Date:</b> 6/14/2019
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CAPA Determination	
N/A	
Is a CAPA Required? (check one)	
YES _____ New CAPA# Assigned: _____	NO <u>X</u> _____
<b>Rationale:</b> Part functions as intended and no further action is required.	

NCR Approval	
Print Name / Title:	Gabriella Levine, Hardware and Systems Lead
Signature:	
Date:	2019-06-24

REWORK Determination
Applicable? Yes _____ No _____ N/A <u>X</u> _____
Rework Protocol Title: NA



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<b>Protocol #:</b> NA		<b>Revision:</b> NA	
<b>Description:</b> NA			
<b>Approver Name:</b>		NA	
<b>Signature:</b>		NA	
<b>Date:</b>		NA	
<b>Rework Protocol</b>			
<b>Rework Work Instruction:</b> NA			
<b>Predefined Acceptance Criteria:</b>		NA	
<b>Results (Select one):</b>		<b>PASS</b> <b>FAIL</b>	
<b>Test report reference:</b>		NA	
<b>Summary:</b> NA			
<b>MRB Approver Name and Title:</b>		NA	
<b>Approval Signature:</b>		NA	
<b>Date:</b>		NA	

<b>Remain in non-conforming state:</b> <b>Use As Is, Return to Supplier, Lab Use Only, Scrap</b>
<b>Additional Information for Product Disposition – Use As Is</b>
<b>Applicable? Yes</b> <u>  X  </u> <b>No</b> <u>      </u> <b>N/A</b> <u>      </u>



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<b>Rationale for Disposition: Use As Is</b>		The tool still functions as intended, to align the connector on the PCBA within the bioamp enclosure. Tool was tested with many production enclosure parts and no fit issues were realized. Non-conformances are not expected to impact assembly nor finished product quality.
<b>DMR / DHR Ref:</b>	NA	
<b>Additional Information for Product Disposition – Return to Supplier</b>		
Applicable? Yes _____ No _____ N/A <u>X</u>		
Return to Supplier Authorization Number, if applicable:		
<b>Additional Information for Product Disposition – Lab Use Only</b>		
Applicable? Yes _____ No _____ N/A <u>X</u>		
<b>Rationale:</b>		
<b>Labeled “Lab Use Only”?</b> (check one)	YES _____ NO _____	<b>Material Location:</b> NA
<b>Confirmed by Signature:</b>	NA	
<b>Date:</b>	NA	
<b>Additional Information for Product Disposition – Reject to Scrap</b>		
Applicable? Yes _____ No _____ N/A <u>X</u>		
<b>Proper Disposal?</b> (check one)	YES _____ NO _____	<b>Rationale:</b> NA



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<b>MRB Approver Name and Title:</b>	NA
<b>Approval Signature:</b>	NA
<b>Date:</b>	NA