

 iNEMI Medical Components - MLCCs		Failure Mode and Effects Criticality Analysis			
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### 1.0 PURPOSE

This document presents the Failure Modes and Effects Analysis (FMEA) for medical grade MLCCs. This document is a product/component FMEA, not a process FMEA.

### 2.0 REVISION INFORMATION

00 Draft: iNEMI Medical Grade Components – MLCCs

### 3.0 FAILURE MODES AND EFFECTS CRITICALITY ANALYSIS (FMECA)

FMECA is a procedure by which each potential failure mode for a given component within the system is analyzed to determine the effects on the system, potential risk to the patient or user, failure causes, and associated prevention controls. The FMECA Worksheet addresses each of these issues. Each section of the worksheet is described below.

#### 3.1 Component

The Component is the device or sub-assembly whose potential Failure Mode is being analyzed.

#### 3.2 Function

The Function describes how the component works within the system.

#### 3.3 Failure Mode

The Failure Mode is the manner by which component failure is observed or characterized.

#### 3.4 Potential Effect(s)

A Potential Effect is the consequence a Failure Mode has on the safety or functionality of the device.

#### 3.5 Severity

Severity is the degree of patient harm or loss of function based on the Potential Effect of each Failure Mode, as follows:

- 5 = Likely patient harm
- 4 = Nonfunctional device and/or potential patient harm
- 3 = Nonfunctional device
- 2 = Degradation of device functionality
- 1 = Nuisance or no noticeable effect

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### 3.6 Frequency

Frequency is the probability that a particular Failure Mode will occur, as follows:

- 5 = Frequent
- 4 = Reasonably probable
- 3 = Occasional
- 2 = Remote
- 1 = Extremely unlikely

### 3.7 Detectability

Detectability is the likelihood of a failure reaching the customer or patient, or the chance that the failure will be undetected, as follows:

- 4 = Failure undetected during normal operation
- 3 = Will be detected after being implanted during normal operation
- 2 = Will be detected prior to completion of being implanted
- 1 = Will find failure prior to shipment

### 3.8 Risk Index

The Risk Index is defined as the product of the Severity, Frequency, and Detectability.

### 3.9 Potential Cause(s)

Potential causes are the processes, design defects, quality defects, and manufacturing defects which are the basic reasons for the Failure Mode. The Potential Causes are classified as follows:

- X = Component failure
- Y = Process Failure (workmanship, process conditions, quality control, etc.)
- Z = User mishandling (exposure to moisture, excessive mechanical shock, etc.)

### 3.10 Prevention/Controls

Prevention/Controls are the design provisions, components, process controls, testing, inspections, and labeling which will ensure that the potential Failure Mode is prevented or detected. The Prevention/Controls are classified as follows:

- A = Verification or validation testing
- B = Training and process instructions
- C = QC inspection
- D = In process acceptance testing
- E = Labeling

## 4.0 FMECA RESULTS

The FMEA analysis for the device is detailed in the worksheets that follow. The highest risk index value obtained during the analysis was associated with the epoxy coating used to encapsulate the transducer windings. The potential failure of the coating epoxy had a risk index of 18, out of a worst case value of 100. The potential effect of a single point coating failure was a “no output” effect on the device. A “no output” failure of the device is considered a fail-safe mode of the device, as it produces no physical harm or injury to the patient. Appropriate preventions and controls have been applied to this component.

## 5.0 CONCLUSIONS

The results of the FMECA analysis indicate that the intended design of the device is considered acceptable. The prevention and control provisions are considered adequate for initiation of a clinical investigation and for commercial distribution.

The most significant potential failure mode of the device is a “no output” condition, which produces no hazard to the patient.

Component	Function	Failure Mode	Potential Effects(s)	S	F	D	Risk Index	Potential Cause(s)	Prevention /Controls
Medical Grade MLCC	Metal Layers – Terminations	Unsolderable plating material	Open circuit	3	2	1	6		
			Cold solder joint	2	2	3	12		
		Defects in plating material	Delamination	3	2	3	18		
			Open circuit	3	2	1	6		
		Defects in barrier layer	Increased ESR	1	1	4	4		
			Voiding	1	2	2	4		
		Poor Cohesion/Adhesion of the underlying material Ag or Cu	Open circuit	3	2	1	6		
			Poor shear strength	2	2	2	8		
			Delamination	3	2	3	18		
		Oxidation of terminations	Poor solderability	3	2	1	6		
	Mechanical	Dimensions out of spec	Lack of mechanical fit	2	1	1	2		
			Open circuit	3	2	1	6		
			Short circuit	3	1	1	3		
			Potential arcing path	3	1	2	6		
		Termination bandwidth out of spec	Open circuit	3	2	1	6		
			Short circuit	3	1	1	3		









