# Purpose and Scope

The purpose of this document is to outline the requirements for a Design Failure Modes and Effects Analysis (DFMEA) of the IPG Models 2408 and 2412 and EPG Model 4300 designs. This analysis is focused on electrical aspects of the IPG and EPG: a separate DFMEA was completed for mechanical failure modes. The main objectives are to identify potential and known failures in normal and single fault conditions, to identify cause and effect of each condition and provide specific mitigations.

This DFMEA report will be re-assessed as appropriate, based on design changes and product performance (e.g., complaints, MDRs, and observations from the field).

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# Reference Documents

* FDA 21 CFR 803 Medical Device Reporting
* ISO 14971:2012 Medical Devices – Application of risk management to medical

devices

* QAQP 0001 Document Control Procedure
* QAQP 0047 FMEA Procedure
* EESP 0071 24-Channel Implantable Pulse Generator Functional

Specification

* SWSP 0112 IPG and EPG Software Requirements Specification
* MERE 0331 Model 2408 and 2412 IPG Battery Short Circuit Testing
* EEPR 0181 IPG Manufacturing Board Test Protocol
* EEPR 0182 IPG Manufacturing Device Test Protocol
* SWSP 0116 IPG and EPG Software Design Specification
* 1330-000054 Assembly Drawings
* 1320-000054 (layout)
* 1310-000058 (schematic)
* 1100-000178 (BOM)

# Definitions

Harm – Physical injury and/or damage to health or property.

Hazard – Potential source of harm.

Severity – The estimated consequence of the failure.

Risk – Probable rate of occurrence of a hazard causing harm and the degree of the severity of the harm.

Part Assembly Name - Name of assembly, part, or section of design documentation under evaluation

Function - Intended function of Part Assembly Name

Failure Mode – The way in which the function under evaluation fails.

Effect of Failure – The effect the failure mode has on the environment, next user, end user, process, etc. whichever is appropriate.

Cause of Failure – What conditions can bring about the failure mode. Sometimes a cause-of-cause is more easily identified or mitigated. In this case, cause-of-cause is identified and controlled.

Occurrence frequency – The probability that the given failure mode will occur.

Failure Detection – The probability that the problem will be detected prior to device use. Both detection during the manufacturing process and by the end user are considered.

Risk Priority Number (RPN) – Provides an indication of the relative priority of the failure mode. (RPN = occurrence\*severity\*detection)

Safety – Freedom from unacceptable risk or harm.

Malfunction – Failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in labeling. The intended performance refers to the intended use for which the device is labeled or marketed. (Reference 21 CFR 803.3(n).)

Serious injury – (1) injury or illness that is life threatening; (2) results in permanent impairment of body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention to precluded permanent impairment of a body function or permanent damage to a body structure. (Reference 21 CFR 803.3(bb) (1).)

Project Engineer – The QIG Group employee responsible for overseeing an assigned project. This includes identifying all documents that are affected by the project and ensuring that required actions to those documents are accomplished.

# Responsibility

## Participants

Table Participants

| **Name** | **Title** | **Primary Responsibility** |
| --- | --- | --- |
| Jeff Weisgarber | Design Engineering Manager | Project Engineer, Develop FMEA |
| Bernie Bosley | Risk Management Consultant | FMEA input from Risk Management & Quality |
| Lisa Jorgenson | Design Assurance Engineer | Design Assurance |
| Ben Cottrill | Project Lead | Project Lead, IPG System |
| Mike Labbe | Product Development Director | Development, IPG and Externals |
| Soheyl Pourmehdi | Design Engineer | Development, IPG and Externals |

## Meetings

Table Meetings

| **Date** | **Agenda** |
| --- | --- |
| 9/8/2010 | Kick-off Meeting, Review Procedure |
| 1/18/2012 | Start FMEA analysis to EESP 0071 |
| 1/25/2012 | Continue FMEA analysis to EESP 0071 |
| 2/8/2012 | Continue FMEA analysis to EESP 0071 |
| 2/24/2012 | Continue FMEA analysis to EESP 0071 |
| 2/29/2012 | Continue FMEA analysis to EESP 0071 |
| 3/14/2012 | Continue FMEA analysis to EESP 0071 |
| 3/23/2012 | Continue FMEA analysis to EESP 0071 |
| 3/28/2012 | Continue FMEA analysis to EESP 0071 |
| 4/4/2012 | Continue FMEA analysis to EESP 0071 |
| 10/3/2012 | Continue FMEA analysis to EESP 0071 |
| 10/4/2012 | Continue FMEA analysis to EESP 0071 |
| 10/9/2012 | Continue FMEA analysis to EESP 0071 |
| 12/18/2013 | Continue FMEA analysis to EESP 0071 |
| 12/19/2013 | Continue FMEA analysis to EESP 0071 |

# General Requirements

FMEA is documented in accordance with Document Control Procedure, QAQP 0001.

# Procedure

## Review the various possible hazards. These include energy hazards, biological hazards and hazards resulting from functional failure, maintenance and aging. These lists are intended to provide an aide-mémoire in identifying possible failure modes.

* 1. Energy hazards include electricity, heat, mechanical force, ionizing radiation, non-ionizing radiation, electromagnetic fields, moving parts, suspended masses, patient support device failure, pressure vessel rupture, acoustic pressure, vibration, and magnetic fields.
  2. Biological hazards include bio-contamination, bio-incompatibility, incorrect formulation, toxicity, allergenicity, mutagenicity, teratogenicity, carcinogenicity, infection, pyrogenicity, inability to maintain hygienic safety, and degradation.
  3. Environmental hazards include electromagnetic interference, inadequate supply of power or coolant, restriction of cooling, likelihood of operation outside prescribed environmental conditions, incompatibility with other devices, accidental mechanical damage, and contamination due to waste production and / or device disposal.
  4. Incorrect output of energy or substances hazards include electricity, radiation, volume, pressure, supply of medical gases, and supply of anesthetic agents.
  5. Hazards related to the use of the device include inadequate labeling, inadequate operating instructions, inadequate specification of accessories, inadequate specification of pre-use checks, over complicated operating instructions, unavailable or separated operating instructions, use by unskilled/untrained personnel, reasonably foreseeable misuse, insufficient warning of side effects, inadequate warning of hazards likely with re-use of single-use devices, incorrect measurement and other metrological aspects, incorrect diagnosis, erroneous data transfer, misrepresentation of results, incompatibility with consumables/accessories/other devices.
  6. Inappropriate, inadequate, or over-complicated user interface hazards include mistakes and judgment errors, lapses and cognitive recall errors, slips and blunders (mental or physical), violation or abbreviation of instructions, complex or confusing control system, ambiguous or unclear device state, ambiguous or unclear presentation or settings, measurements, or other information, misrepresentation of results, insufficient visibility, audibility, or tactility, poor mapping of controls to action, poor mapping of displayed information to actual state, and controversial modes or mappings as compared to existing equipment.
  7. Hazards arising from functional failure, maintenance and aging include inadequacy of performance characteristics for the intended use, lack of or inadequate specification for maintenance, inadequate maintenance, and lack of adequate determination of end of device life, loss of mechanical integrity, inadequate packaging, improper use/reuse, and deterioration of function.

## Part Identification – Identify the assembly or component being analyzed.

## Part Function – Describe the part function in relationship to the device, assembly, or therapy.

## Failure Mode – Describe each possible failure mode. No judgment is to be made on the likelihood of failure only on how it could fail. A review of past design FMEAs, quality history, warranty data, durability data, and reliability problems on comparable components are a recommended starting point.

## Effect of Failure – Describe the effect of the failure mode. What does the user or system experience as a result of the failure mode just listed?

## Cause of Failure – Analyze what conditions can bring about the failure mode.

## Estimate the occurrence frequency – Estimate the probability that the given failure mode will occur using a ranking scale of 1 to 5, where 1 indicates a low probability of occurrence whereas a 5 means a near certainty of occurrence as shown in . Probability in means the statistical proportion outside the specification limits.

## Severity – Evaluate the severity or estimated consequence of the failure on a scale of 1 to 5, where 1 means a minor nuisance whereas a 5 indicates a severe, total failure. See .

## Failure Detection – Estimate the probability that the problem will be detected prior to device use – either during the manufacturing process or by the user. A low number indicates that detection is likely to occur; in contrast, a high number indicates that the detection is less likely to occur prior to device use. See Table 7.

## Calculation of Risk Priority Number (RPN) – The RPN index is calculated by multiplying the rankings of occurrence, severity, and detection. The RPN index obtained provides an indication of the relative priority of the failure mode. This FMEA uses the template version (QAQP 0047, revision 1.10) that was active when the FMEA was started. One of the updates implemented in revision 1.11 was to list both an initial RPN & final RPN. This FMEA does not list the initial RPN for each failure mode, since the RPN values were updated as mitigations were identified and implemented.

## Evaluate all RPNs relative to each other.

## Identify mitigation action to reduce risk for relatively high RPNs or observed trends.

### Risk reduction strategies include but are not limited to: specification changes, design changes, manufacturing process changes, increased testing in design phase, increased testing in manufacturing process, and changes to product labeling.

### For product/projects in the design phase, corrective/preventive action identified through the risk management process may be managed through the design controls process (i.e. do not need to be managed through the CAPA process).

### For risk mitigation measures that require changes to the design, or additional features or specifications for the product, a review of the Design Input Specifications will be conducted to ensure that appropriate updates are made as necessary to reflect these changes. This will ensure that these mitigation measures are tracked through the design process and included in design verification or validation testing.

## Mitigation action to address the cause of the failure mode. It should be considered for RPNs determined to be unacceptable. Rationale for RPN number used as a “cut-off” or other approach for defining “unacceptable” risk level should be in the FMEA report. (Number may vary for each FMEA.)

## After completion of risk mitigation measures, risk should be reevaluated. Repeated risk mitigation and risk re-evaluation shall occur until residual risk has been determined to be acceptable or benefits of the product are deemed to outweigh residual risks.

# Sample Size Guidance

The following is for guidance on sample sizes to be used in design verification testing (DVT). Sample size may vary for a given device depending on what functions is being tested. Sample sizes are justified in the applicable test plan and justifications must be statistically valid. RPNs resulting from FMEA are one form of justification for sample size

Table Sample Size Guidance

|  |  |  |
| --- | --- | --- |
| RPN | Comment | Attribute Sample Size Guidance |
| 65 - 125 | There is a reasonable potential for harm from device use. Sample sizes less than 59 require risk justification | ≥ 59 |
| 28 - 64 | Potential for harm due to failure is not remote. Sample sizes less than 22 require risk justification | ≥ 22 |
| 9 - 27 | Failure modes show early in process and/or rarely emerge in clinical use | 5 - 22 |
| 1 - 8 | Failure modes unlikely to lead to harm | 0 - 5 |

Note: Above sample size guidance is in relation to attribute data only. Other statistical methods may be employed to determine sample size when variables data are available.

# Ranking Criteria

## Occurrence

Table Occurrence Ranking Criteria

| **Criteria** | **Estimated Probability in device-months (Note 1)** | **Estimated Probability in 1-year use** | **Ranking** |
| --- | --- | --- | --- |
| Remote probability or occurrence | x ≤ 1/12,000,000 | x ≤ 1/1,000,000 | 1 |
| Low probability or occurrence | 1/12,000,000 ≤ x < 1/1,200,000 | 1/1,000,000 ≤ x <1/100,000 | 2 |
| Moderate probability of occurrence | 1/1,200,000 ≤ x < 1/12,000 | 1/100,000 ≤ x <1/1,000 | 3 |
| High probability or occurrence | 1/12,000 ≤ x < 1/12 | 1/1,000 ≤ x <1 | 4 |
| Very High probability or occurrence | 1/12 ≤ x | 1 ≤ x | 5 |

Note 1: Occurrence is the rate of failure of the failure cause with the stated mitigation in place (if there is one). Occurrence is categorized in device-months. This number can also be used as total failure rate by multiplying it by the expected life. For example, it the failure rate is 0.01 and the expected service life is 12 months, then the total failure rate is 0.12 (12 \* 0.01).

## Severity

Severity of specific hazards was considered separately for the IPG and the EPG based on the ranking criteria below. In a few specific cases, the severity for EPG failures was decreased by one level relative to the IPG either due to the temporary nature of the EPG (e.g. RF performance or deterioration of lead contacts), or due to the fact that the EPG can be replaced without a revision surgery (e.g. channel loss) as shown in Table 6.

Table Severity Ranking Criteria

|  |  |
| --- | --- |
| **Criteria** | **Ranking** |
| No or minor affect to device operation or performance; impact may not be noticed by user. No affect to patient or operator safety. Device faults in a manner that presents a nuisance or inconvenience to user but does not result in loss of functionality and does not affect patient or user safety. | 1 |
| Device faults (loss of some functionality, but not device failure) partially or intermittently, in a safe manner. Device faults consistently, in a safe manner performance. | 2 |
| Device fails (inoperable) in safe manner. Serious injury to patient and/or operator unlikely. | 3 |
| Device faults fails in manner that may be unsafe. Serious injury to patient and/or operator possible. Intervention may be required to prevent non-serious or non-permanent injury. | 4 |
| Device fails in unsafe manner. Death or serious injury or permanent injury to patient and/or operator or intervention required to prevent serious injury or death. | 5 |

Table Specific Failure Effects and Severities

| Failure Effect | IPG Severity Ranking | EPG Severity Ranking |
| --- | --- | --- |
| Excessive heat – severe \* | 4 | 4 |
| Tissue damage | 4 | 4 |
| Bioincompatible\* | 3 | 2 |
|  |  |  |
| Unintended effect\* [General] | 3 | 3 |
| Stimulation compromised, unintended or intermittent stimulation (includes overstim, surgery required for IPG) | 3 | 2 |
| Stimulation on wrong channel or to can, correctable without surgery | 2 | 2 |
|  |  |  |
| Electrical leakage (Net DC) leading to electrode corrosion (damage to leads, assumes EPG in use with trial lead) | 3 | 2 |
|  |  |  |
| Premature IPG failure, explant, unintended revision surgery\* | 3 | N/A |
| Unable to control IPG stimulation or communicate (including loss of MICS) | 3 | N/A |
| Loss of Stimulation (IPG) | 3 | N/A |
| Unable to recharge | 3 | N/A |
|  |  |  |
| IPG/EPG failure not requiring surgery (product can still support intended use or be replaced non-surgically) | 2 | 2 |
| Under stimulation (lower than desired or outright loss of stimulation) that is correctable without surgery. | 2 | 2 |
| Excess recharge time or increased recharge frequency (or battery replacement for EPG) | 2 | 2 |
| Reduced RF performance | 2 | 1 |
| Loss of stimulation (EPG) | N/A | 2 |
| Unable to communicate with EPG | N/A | 2 |
| Unable to use magnet off | 2 | N/A |
|  |  |  |
| Poor diagnostics | 2 | 2 |
| Implant difficulty, unable to assemble system, unable to implant | 1-2 | 1-2 |
| Physician or patient inconvenience/dissatisfaction | 1 | 1 |

\* These effects are expressed in terms of patient hazard. See EEEX 0071 SCS Hazard Summary for definition.

## Detection

Table Detection Ranking Criteria

| **Criteria** | **Ranking** |
| --- | --- |
| Remote likelihood that product would be used without detecting this failure condition, since it is easily detectable in manufacturing or by user. | 1 |
| Low likelihood that product would be used without detecting this failure condition, since it is easily detectable in manufacturing or by user | 2 |
| Moderate likelihood that product would be used without detecting failure condition, since the failure effect is more subtle in nature or is intermittent. | 3 |
| High likelihood for use of product without detecting failure condition, defect not readily detectable. | 4 |
| Very High likelihood that failure condition will not be detected prior to failure during use. Failure is Undetectable through inspection or testing or latent failure mode | 5 |

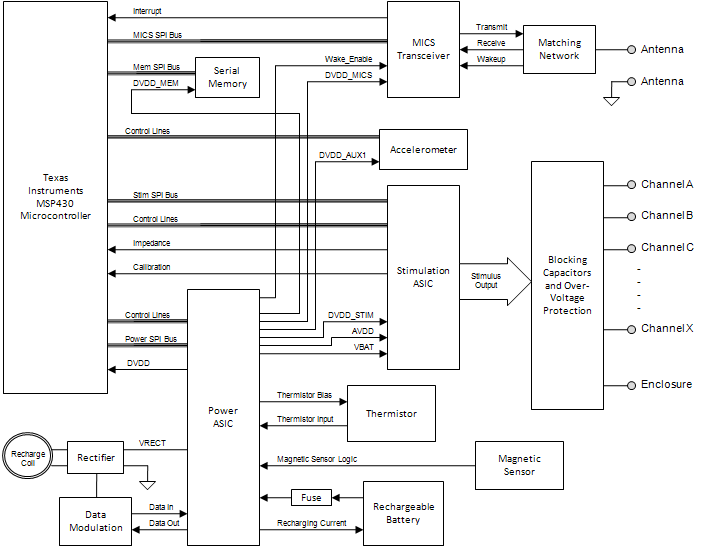
**Table 8 Risk Priority Number (RPN) Summary of RPN >27**

| **RPN** | **Total # of FMEA line items with this RPN** | **Summary** | **Mitigation Impact** |
| --- | --- | --- | --- |
| 27 | 4 | 1. VBATF high impedance 2. VBATF open circuit 3. Blown fuse due to high current 4. Intermittent loss vbatf |  |
| 30 | 6 | 1. Fuse blown 2. Cap leakage from aging 3. Defib / cautery breaks tvs [short] 4. Defib / cautery breaks tvs [latent] 5. Aging tvs [latent] 6. Fluid ingress detunes antenna | Failure modes have been assessed & mitigated. Residual risk has been reduced to as low as reasonably practicable. |

# Device Description and Critical Subsystems Analyzed

## IPG Electrical Overview

The IPG is comprised of various electrical functional areas, as shown in the figure below:

****

**Block Diagram of 24-Channel Implantable Pulse Generator**

## PCB

The PCB is used to provide a substrate and interconnects for the components of the IPG subsystems. The flex fingers of the IPG are analyzed in this section while the interconnects are analyzed for each subsystem.

## Power Management

The power architecture consists of the rechargeable battery, the Power ASIC, recharge coil, rectifier, and data modulation circuitry. The rechargeable battery (analyzed extensively outside this FMEA) provides raw power to the IPG. The recharge coil and rectifier accept power from the transcutaneous power link and convert it to a DC voltage, while the data modulation circuit will uses the transcutaneous link to transfer data to and from the external charger. The Power ASIC provides control of the recharge process, battery protection, and power for the digital, analog, and high-voltage components of the system.

## Microcontroller and Memory

The microcontroller runs the firmware and controls the IPG’s output. It interfaces to other functional blocks to monitor IPG status, to send and receive communications, and to drive the channel configuration and output waveforms.

## Stimulation and Protection Circuitry

The Stimulation ASIC produces the waveforms for stimulation. It provides current steering capabilities to allow control of nerve fiber recruitment. The Stimulation ASIC also has the ability to perform electrode-to-electrode and electrode-to-enclosure impedance measurements. The Stimulation ASIC has several built-in error detection mechanisms to provide additional safety.

The protection circuitry enhances safety for both the patient and the IPG itself. It includes protection from electrostatic discharge (ESD) and over-voltage conditions (from defibrillation pulses and electrocautery). It also includes EMI filters to minimize the effect on the IPG by magnetic fields generated during MRI.

## RF Communications

The MICS transceiver and matching network provide a wireless communications interface to several external devices. The transceiver receives commands and returns data while automatically handling data flow, RF channel control, error correction, and wakeup detection. The matching network provides the interface to the MICS antenna, which is located in the header of the IPG and is a simple trace loop on the EPG.

# Design FMEA

## PCB

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IPG 2412/2408**  **EqPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| **Flex Fingers**  Output channels | Electromechanical connection between circuit board & FTs | Flex finger trace opens permanently. | Loss of output channel. Patient feels difference in stimulation. | Diagnostic impedance measurement |  | Solder joint failure (finger to FT) | 2 | N/A | 1 | 2 | 4 | N/A | Impedance check deactivates programs that use channels with open-circuit flex fingers [swsp 0112 #624] 100% electrical test in manufacturing (EEPR 0182) | x |
| Cycle fatigue causes trace to break | 2 | N/A | 1 | 2 | 4 | N/A | Impedance check deactivates programs that use channels with open-circuit flex fingers [swsp 0112 #624, #768] |  |
|  |  |  |  |  |  | Flex finger trace designed as wide as possible  (1320-000054 layout) |  |
|  |  |  |  |  |  | Polyimide layers as thin as possible with trace centered between them (1330-000054) |  |
| Flex finger trace opens intermittently | Momentary loss of output channel. Patient occasionally feels difference in stimulation. | Diagnostic impedance measurement |  | Solder joint failure (finger to FT) | 2 | N/A | 3 | 2 | 12 | N/A | Impedance check deactivates programs that use channels with open-circuit flex fingers. May only catch occasionally. [swsp 0112 #624, #768] 100% electrical test in manufacturing (EEPR 0182) | x |
| Cycle fatigue causes trace to break | 2 | N/A | 3 | 2 | 12 | N/A | Impedance check deactivates programs that use channels with open-circuit flex fingers [swsp 0112 #624, #768] |  |
| Flex finger trace designed as wide as possible 1320-000054 (layout) |  |
| Polyimide layers as thin as possible with trace centered between them 1330-000054) |  |
| Flex finger traces shorted. | Stimulation current is applied to unintended channel(s). | Change in the feeling of stimulation. |  | Loose metal or broken solder joint. | 2 | N/A | 4 | 1 | 8 | N/A | Ability to do channel-to-channel impedance measurements using clinician programmer.  [IPG req 1620, SWSP 0090 F7320], 100% electrical test in manufacturing (EEPR 0182) | x |

## Power Management Subsystem

| **IPG 2412/2408**  **EPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Power ASIC**  DVDD power supply | Provides digital power to Power ASIC, MSP430, and various other circuit elements | Short of the DVDD supply capacitor (C32) | Loss of DVDD supply; possibly high current drain from battery;  Stim compromised |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | Evaluation testing of battery short demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report). 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | x |
| Open of the DVDD supply capacitor | Noisy DVDD supply; possible significant drop of DVDD voltage under high current loads, Stim compromised |  |  | Random failure or defect; PCB trace or solder joint failure | 2 | 2 | 5 | 1 | 10 | 10 | Black-out reset of MSP430 would stop actively running stimulation. (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | x |
| PASSW\_CL input stuck high | Pass switch enabled at all times; Pluto buck/boost disabled; loss of DVDD when VBAT < 2.70V, Inconvenience of reduced battery life. |  |  | Random failure or defect | 1 | 1 | 5 | 1 | 5 | 5 | Battery shutdown thresholds are all above 2.75V, and PASSW\_CL will be high during idle mode, so no anticipated patient impact from this failure. (EESP 0071), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| PASSW\_CL input stuck low | Pass switch never enabled; Pluto buck/boost enabled at all times; higher current during idle mode Inconvenience of reduced battery life | Patient may notice decreased battery run time. |  | Random failure or defect | 1 | 1 | 5 | 1 | 5 | 5 | Due to less efficient buck/boost operation during idle mode, battery run time will be reduced, though impact is likely minimal, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| PASSW\_CL input floating | Floating may cause IPG to switch between pass switch and buck/boost at unpredictable times. Inconvenience of reduced battery life | Patient may notice decreased battery run time. |  | PCB trace or solder joint failure | 1 | 1 | 5 | 1 | 5 | 5 | Due to less efficient buck/boost operation during idle mode, battery run time will be reduced, though impact is likely minimal, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| VDIG pin on Power ASIC becomes no connect or intermittent after power is already up | Loss of VDIG to MSP430 while Power ASIC (and maybe MICS and Stim) remain powered; possible parasitic powering of MSP430 may occur. (Understim, leading to eventual replacement) |  |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | Black-out reset of MSP430 would stop actively running stimulation; MSP430 drives. Stim ASIC reset low almost immediately after coming out of reset (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| VDIG regulator in Power ASIC putting out voltage too high | Damage to MSP430, MICS radio, or Stim ASIC leading to premature failure | Electrical test in manufacturing |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), | x |
| VDIG regulator in Power ASIC putting out voltage too low | Unpredictable operation of MSP430, MICS radio, or Stim ASIC, premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | No additional detection or mitigation required, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| DVDD\_STIM, DVDD\_MICS,  DVDD\_MEM, and DVDD\_AUX1 power supplies | Provides digital power to Stim ASIC, MICS radio, serial FRAM, and accelerometer | DVDD\_STIM, DVDD\_MICS, DVDD\_MEM, or DVDD\_AUX1 shorted to GND | The shorted supply will not be capable of coming up, so its circuit functionality will be lost; DVDD could be dragged down causing a POR. , premature failure and replacement | Patient could detect loss of stimulation or loss of MICS; IPG would detect memory failure. |  | Random failure or defect | 3 | 2 | 4 | 1 | 12 | 8 | black-out reset of MSP430 would stop actively running stimulation (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| DVDD\_STIM, DVDD\_MICS, DVDD\_MEM, or DVDD\_AUX1 shorted to DVDD | Cannot power down supplies even when requested by MSP430. Excess recharge time or increased recharge frequency (or battery replacement for EPG) | Patient may notice decreased battery run time. |  | Random failure or defect; PCB trace or solder joint error | 2 | 2 | 5 | 1 | 10 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Problem with Power ASIC ENABLE1 register | Loss of control of DVDD\_STIM, DVDD\_MICS, DVDD\_MEM, and DVDD\_AUX1 supplies; possible parasitic powering | Data read-back after writing; patient may detect loss of stimulation or MICS chip |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Increase in switch resistance over time | Power glitches could appear at one of the supplies. premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | No additional detection or mitigation required |  |
| Power SPI interface | Allows data transfer between MSP430 and Power ASIC | CS stuck asserted or de-asserted | MSP430 can’t read or write to Power ASIC; loss of power function control. premature failure and replacement | Data read-back after writing |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Inadvertent assertion of CS | Possible incorrect data transfer. premature failure and replacement |  |  | FW error or noise | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| CS line floating | MSP430 can’t read or write to Power ASIC; loss of power function control premature failure and replacement | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK stuck in one position (high or low) | No data transfer; loss of power function control. premature failure and replacement | Data read-back after writing |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK signal is irregular | Incorrect data transfer; loss of power function control. premature failure and replacement | Data read-back after writing |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK line floating | Incorrect data transfer; loss of power function control. premature failure and replacement | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| SDI or SDO stuck in one position (high or low) | Incorrect data transfer; loss of power function control. premature failure and replacement | Data read-back after writing |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| SDI or SDO line floating | Incorrect data transfer; loss of power function control. premature failure and replacement | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| AVDD power supply | Provides analog supply for Stim ASIC | Short of the AVDD supply capacitor (C33) | Loss of AVDD supply and Stim ASIC functionality; possibly high current drain from battery. premature failure and replacement | Stimulation output check at start of program; Patient would detect loss of stimulation. |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | If capacitor fails while stimulation is active, output would stop due to lack of power for Stim ASIC internal references. 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Open of the AVDD supply capacitor | Noisy AVDD supply and stimulation output; possible significant drop of AVDD voltage premature failure and replacement | Stimulation output check at start of program; Patient would detect loss of stimulation. |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | if capacitor fails while stimulation is active, output would stop due to lack of power for Stim ASIC internal references. 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| VANA pin on Power ASIC becomes no connect or intermittent after power is already up | Loss of VANA to Stim ASIC while stimulation is active; possible complete or intermittent loss of stimulation output. premature failure and replacement | Stimulation output check at start of program; Patient would detect loss of stimulation. |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| VANA regulator in Power ASIC putting out voltage too high | Damage to Stim ASIC. premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| VANA regulator in Power ASIC putting out voltage too low | Unpredictable operation of Stim ASIC. premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Problem with Power ASIC ENABLE1 register | Loss of control of VANA supply. premature failure and replacement | Data read-back after writing. |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), | x |
| Power buck/boost converter and pass switch | Converts battery voltage to a level acceptable for Power ASIC’s linear regulators | Failure of external inductor (L30) or output capacitor (C31) | Buck/boost converter will not work; DVDD will fail. (Understim) premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | X |
| PASSW\_CL input stuck high | Pass switch closed at all times and buck/boost disabled; potential power issues when battery voltage drops to 3.0V. Patient may never notice change in IPG operation. Inconvenience of shorter battery life. |  |  | Random failure or defect | 2 | 2 | 5 | 2 | 20 | 20 | No additional detection required; If pass switch control is stuck, no impact to stimulation due to stim cut-off threshold of 3.7V. [EESP 0071 FRS 0863], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| PASSW\_CL input stuck low | Pass switch open at all times and buck/boost always enabled; higher battery current in Idle Mode. Patient may notice reduced run time between charges. Inconvenience of shorter battery life. | Patient may notice reduced run time between battery charges. |  | Random failure or defect | 2 | 2 | 4 | 2 | 16 | 16 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| PASSW\_CL floating | Random switching between pass mode and buck/boost mode. premature failure and replacement |  |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Power VBATF input | Brings fused battery voltage into Power ASIC for power | Intermittent connection for VBATF pins | Loss of all DVDD and AVDD power when open. Patient would notice random resetting or stim shutting off. premature failure and replacement | Patient would notice IPG “shutting off”. |  | PCB trace or solder joint failure | 3 | 2 | 3 | 2 | 18 | 12 | Two solder contacts for VBATF (1330-000054).  100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| VBATF node shorted to GND | Would likely cause fuse to blow; can only power up IPG over TETS. Patient would notice IPG off all the time except when TETS is present. premature failure and replacement | If DVDD is up, fuel gauge will indicate dead battery. |  | Random failure or defect | 3 | 2 | 3 | 2 | 18 | 12 | Stimulation would be disabled by fuel gauge; fuse would likely blow to prevent high battery current. Evaluation testing of battery short demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| VBATF node has high impedance | VBATF voltage drops during high-current cases. Patient may notice stim shutting off unexpectedly. premature failure and replacement |  |  | Random failure or defect; PCB trace or solder joint and/or weld failure | 3 | 2 | 3 | 3 | 27 | 18 | Multiple VBATF pins on Power ASIC (EESP 0086). 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | X |
| VBATF node becomes open-circuit | Loss of power to supplies; IPG function lost except when TETS is present. Patient would lose ability to turn on stim. premature failure and replacement | Patient would notice loss of IPG function. |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 3 | 3 | 27 | 18 | Stimulation would stop if VBATF net becomes open-circuit; multiple VBATF pins on Power ASIC. 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Fuse | Protects battery from large load currents | Fuse blows due to high current | Patient would notice IPG function is lost. premature failure and replacement | Patient would notice loss of IPG function. |  | High current into VBATF node | 3 | 2 | 3 | 3 | 27 | 18 | Evaluation testing of battery short demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report). 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Intermittent connection of either fuse pin | IPG loses power intermittently, but can sometimes be brought out of Storage Mode by PPC. Patient will notice intermittent loss of IPG function. premature failure and replacement | Patient would notice intermittent loss of IPG function. |  | Solder joint failure | 3 | 2 | 3 | 3 | 27 | 18 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Fuse shorted so that it does not blow. Battery would not be protected from a short at VBAT to GND. If short occurs, battery would be exposed to high-current load under double-fault condition. | High-current protection is lost. If VBAT is shorted to GND, battery terminals would be shorted under double-fault condition. As described in MERE 0331, heating is expected to stay below 42°C. |  |  | Random failure or defect; conductive substance bridging fuse pins | 3 | 4 | 5 | 1 | 15 | 20 | No additional detection required. Evaluation testing of battery short demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report). 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Fuse resistance goes up over time. Patient shouldn’t notice change in IPG behavior. | Decrease in performance of power supplies |  |  | Change in fuse characteristics over time. | 2 | 1 | 5 | 2 | 20 | 10 | No additional detection or mitigation required. |  |
| Fuse blows at much lower current than its rating. | Patient would notice IPG function is lost. premature failure and replacement |  |  | Component defect | 3 | 2 | 5 | 2 | 30 | 20 | Evaluation testing of battery short demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report). 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | x |
| Power VBATR input | Brings raw (non-fused) battery voltage into Power ASIC for sensing voltage | Intermittent connection for VBATR pins | IPG loses charge controller and fuel gauge intermittently. premature failure and replacement | Patient may notice odd behavior of IPG power. |  | Solder joint failure | 3 | 2 | 3 | 2 | 18 | 12 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| VBATR node shorted (low impedance) to GND | Unable to measure battery; charging would always stay in Pre-Charge phase. IPG would eventually lose all battery power. premature failure and replacement | Patient would notice inability to charge IPG. |  | Random failure or defect | 3 | 2 | 3 | 2 | 18 | 12 | Pre-Charge phase charging timeouts; stimulation would be blocked from starting; IPG would put itself into Storage Mode. (EESP 0071) 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| VBATR node becomes open-circuit | Unable to measure battery; charging would always stay in Pre-Charge phase. IPG would eventually lose all battery power. premature failure and replacement | Patient would notice inability to charge IPG. |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 3 | 2 | 18 | 12 | Pre-Charge phase charging timeouts; stimulation would be blocked from starting; IPG would put itself into Storage Mode (EESP 0071), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Power UNDERVOLT input | Controls the battery protection switch inside the Power ASIC | UNDERVOLT input stuck high | IPG unable to put itself into Storage Mode. Potential long term battery life reduction | Patient may not notice any change in IPG operation. |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | Verify IPG is in Storage Mode prior to leaving factory. 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| UNDERVOLT input stuck low | IPG stuck in Storage Mode unless powered over TETS. premature failure and replacement | Patient would notice IPG shuts down when TETS not active. |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Tes 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| UNDERVOLT floating | IPG could enter Storage Mode unexpectedly premature failure and replacement. | Patient would notice intermittent operation of IPG. |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 4 | 1 | 12 | 8 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Internal protection switch fails in an open state | IPG stuck in Storage Mode unless powered over TETS. premature failure and replacement | Patient would notice IPG shuts down when TETS not active. |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Internal protection switch fails in a closed state | IPG unable to put itself into Storage Mode. Potential long term battery life reduction | Patient may not notice any change in IPG operation. |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | Verify IPG is in Storage Mode prior to leaving factory. 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Internal protection switch resistance increases | Power glitches could appear on DVDD supply. Inconvenience of occasional reset | Patient may notice occasional resets. |  | Random failure or defect | 1 | 1 | 3 | 1 | 3 | 1 | . Black-out will reset IPG MSP stimulation (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Power BAT\_EN input | Controls the battery protection switch; intended for testing IPG during manufacturing | BAT\_EN input stuck high | IPG potentially unable to be put into Storage Mode, unable to use magnet off. |  |  | Random failure or defect | 2 | 2 | 2 | 1 | 4 | 4 | BAT\_EN has no connection to DVDD external to ASIC; pull-down resistor placed as close to input as possible. 1330-000054, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| BAT\_EN input stuck low | IPG unable to be started during manufacturing test. | Electrical test |  | Random failure or defect | 1 | 1 | 1 | 1 | 1 | 1 | BAT\_EN has no function during normal use of IPG. If this input is stuck low, the xPG will not pass 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Power LDO\_CTL input | Controls the full-power operation of the DVDD supply | LDO\_CTL input stuck high | DVDD supply at full-power at all times; reduced battery life | Patient may notice reduced run time between charges. |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | Low-power states will be checked during electrical test 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| LDO\_CTL input stuck low | DVDD supply in low-power mode at all times; IPG will reset during a high-power state. premature failure and replacement | IPG will reset when entering a high-power state. Patient will notice PORs; stim may not be possible. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | Black-out will reset IPG (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| LDO\_CTL floating | DVDD will switch between high-power and low-power modes unexpectedly; IPG could reset at random times. premature failure and replacement | IPG will reset if DVDD enters low-power mode while the IPG is in a high-power state. Patient will notice PORs; stim may turn off unexpectedly. |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | Black-out will reset IPG (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Power STROBE\_IN input | Drives the STROBE\_OUT output independently from the internal strobe | STROBE\_IN input stuck high | STROBE\_OUT signal high at all times; MICS radio in wakeup mode at all times. Inconvenience of shorter battery life |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| STROBE\_IN input stuck low | STROBE\_OUT signal low except when driven by internal strobe; MICS communications will fail when initiating a session . premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| STROBE\_IN floating | STROBE\_OUT signal driven at unexpected times; possible to lose MICS communications for extended periods. premature failure and replacement |  |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Power STROBE\_OUT output | Drives the MICS WU\_EN pin at a programmed rate or on demand from the MSP430 | Internal strobe timer or other hardware not working | MICS WU\_EN not driven as expected; loss of MICS communications | Patient would lose ability to communicate with IPG over MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Internal strobe not programmed correctly | MICS WU\_EN driven at an incorrect rate; MICS latency could be longer than expected (reduced RF performance) | Patient may notice long latency when sending commands to IPG. |  | Firmware error | 2 | 1 | 4 | 1 | 8 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| STROBE\_OUT fails to be driven by STROBE\_IN signal | MICS WU\_EN not driven as expected; loss of MICS communications |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Power HVISW\_CL\_IN input | Controls the internal input switch for the HVDD boost converter | Internal power switch fails in an open state or HVISW\_CL\_IN input stuck low | Soft-start feature of HVDD start-up lost; possible power glitches as a result due to high current pulled from battery. premature failure and replacement | Power monitor would reset IPG for serious glitches at DVDD |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | Black-out will reset (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Internal power switch fails in a closed state or HVISW\_CL\_IN input stuck high | Input voltage to HVDD supply applied at all times; reduced battery run time. premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | Presence of HVDD output switch prevents voltage from appearing at Stim ASIC channels when stimulation is inactive (EESP 0085), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Internal power switch resistance too high or too low | Soft-start feature would not function as expected; possible high start-up currents. premature failure and replacement | Power monitor would reset IPG for serious glitches at DVDD |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | . Black-out will reset IPG (MSP430x2xx Family User’s Guide SLAU144J–December 2004–Revised July 2013), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| HVISW\_CL\_IN input floating | HVDD input switch opens and closes at unexpected times. premature failure and replacement | Patient would detect loss of stim at unexpected times. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | Stimulation will turn off if switch opens while stimulation is active (EESP 0071) , 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Power HVISW\_CL\_OUT output | Drives the external MOSFET switch for the HVDD boost converter | External MOSFET fails in an open state or HVISW\_CL\_OUT stuck high | High-current input switch for the HVDD converter lost; degraded performance of HVDD supply premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| External MOSFET fails in a closed state or HVISW\_CL\_OUT stuck low | High-current input switch for HVDD closed at all times; reduced battery run time. |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Gate of external MOSFET floating | High-current input switch for the HVDD converter opens and closes at unexpected times. premature failure and replacement |  |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Thermistor | Provides temperature feedback to microcontroller | Provides false over temp | Charging runs slow. Inconvenience of recharge time |  |  | Component failure | 2 | N/A | 3 | 1 | 6 | N/A | No additional detection required  Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Provide false undertemp | Charging runs hot (potential thermal injury) |  |  | Component failure | 4 | N/A | 4 | 1 | 16 | N/A | No additional detection required  Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Fail detectable open / short | Can no longer charge. Premature failure and replacement | Three point measurement detects component failure |  | Component failure | 3 | N/A | 4 | 1 | 12 | N/A | Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182]  Three point measurement detects component failure [1310-000058] | X |
| Magnetic Sensor | Provides hardware based shutoff to power ASIC (5 second presence) | Sensor fails high | IPG stays in storage mode, no stim, revision required. | Patient notices no stim |  | Component failure | 3 | N/A | 5 | 1 | 15 | N/A | Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182 | X |
| Sensor fails low | Unable to turn device off with magnet. Inconvenience of reduced control. | Patient notices unable to turn off stim with magnet |  | Component failure | 2 | N/A | 5 | 1 | 10 | N/A | Turn off stim with PPC or PoP  Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182 | X |
| Quick Stim Off Switch | Brings EPG out of storage mode (stim functionality covered under stim) | Switch fails open or closed | Can’t bring out of storage mode. Replace EPG |  |  | Component failure | N/A | 2 | 1 | 1 | N/A | 2 | 100% electrical test in manufacturing (EEPR 0196) No additional detection required | x |
| Charging Coil | Receives charging power from PPC. Note that communications functionality is secondary, and is covered by modulation circuitry below. | Charging coil failure modes assessed in mechanical design FMEA (MEFM 0021 IPG Mechanical Design FMEA) |  |  |  |  | - | N/A | - | - | - | N/A | See MEFM 0021 IPG Mechanical Design FMEA |  |
| Rectifier | Converts AC power input from coil to DC power for power ASIC | No DC power available for recharge | Unable to charge, revision surgery required | Patient notices unable to charge |  | Component failure | 3 | N/A | 5 | 1 | 15 | N/A | Electrical DVT [EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182 | X |
| Inductive Communications Circuitry (modulator and demodulator) | Detunes coil in event of overheat condition | SW/FW issue plus control of detuning cap fails | Thermal Error | Thermistor check |  | Component failure | 4 | N/A | 1 | 1 | 4 | N/A | Electrical DVT [ EEPR 0153, EERE 0548]  Component selection [1100-000178]  Electrical test [EEPR 0182 | X |
| EPG Battery LED | Shows battery status | Stuck On Green | Understim | Green light is not flashing |  | Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0196) | x |
| Stuck on Red | Patient inconvenience | Red light is not flashing |  | Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0196) | x |
| Stuck on both | Patient inconvenience | Solid color & different color |  | Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0196) | x |
| Stuck off | Understim | Observe light is not on |  | LED burns out | N/A | 2 | 3 | 1 | N/A | 6 | LED selection (1100-000179-03) |  |
| Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0196) | x |

Note 1: Line items identified by “X” in the Mfg. column are mitigation actionsrelated to Manufacturing and/or Process FMEA.

## Microcontroller and Memory

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **IPG 2412/2408**  **EPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| **Microcontroller[[1]](#footnote-1)** | Execute Firmware | Firmware not executed. “Bricked” device. Additional specific failures (e.g. clocks) listed on per-subsystem basis. | Premature failure and replacement | Patient notices stim stuck off or cannot communicate |  | Firmware error | 3 | 2 | 5 | 1 | 15 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Run watchdog timer | Watchdog “stops watching” and fails to notice FW execution locked up | Premature failure and replacement | Patient notices stim stuck off or cannot communicate |  | Component failure | 3 | 2 | 5 | 1 | 15 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Watchdog “keeps barking” repeatedly resetting processor | Premature failure and replacement | Patient notices stim stuck off or cannot communicate |  | Component failure | 3 | 2 | 5 | 1 | 15 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Perform AD conversions | Internal AD or controller failure | Battery Voltages incorrect  Inconvenience around recharge |  |  | Component failure | 2 | 2 | 5 | 1 | 10 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182]  No additional detection required | X |
| Incorrect impedance  (poor diagnostics) |  |  | Component failure | 2 | 2 | 5 | 1 | 10 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182]  No additional detectionrequired | X |
| NV Ram | Stores:   * Configuration Device Parameters (CDP) * Ramp Time * Clinician Programmer (CP) Data * Program Definition * Lead Limits * Active Program Definition\* * Background Impedance Parameters\* * Log Events\*\* * Counters\*\* | Random bit flip | Reprogram – failure not requiring surgery | Internal mem checks |  | cosmic ray | 2 | 2 | 2 | 2 | 8 | 8 | CP restore - SWSP 0090 F7985  Software CRC checks – many reqs in SWSP 0112 and SWSP 0116 |  |
| Outright component failure | Premature failure and replacement | Patient notices IPG no longer works |  | Component failure | 3 | 2 | 5 | 1 | 15 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |
| Flash | Store   * Channel Calibration Data * High Voltage Calibration Data * XPG Identity * Trim Lists * General Calibration Data * Program Constants (Frequency Table) * Pulse Constants | Random bit flip | No impact to patient | Internal mem checks |  | Cosmic ray | 1 | 1 | 2 | 2 | 4 | 4 | Redundant copy  [SWSP 0112 and SWSP 0116] |  |
| Outright component failure | Premature failure and replacement | Patient notices IPG no longer works |  | Component failure | 3 | 2 | 5 | 1 | 15 | 10 | Electrical DVT [EEPR 0153, EERE 0548, EERE 0564]  Component selection [1100-000178]  Electrical test [EEPR 0182] | X |

## Stimulation Subsystem

| **IPG 2412/2408**  **EPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Stim ASIC**  Output stage | Generates current for stimulus pulses | Current source transistor(s) fails as an open-circuit | Less output current than programmed for that channel. Patient may notice decrease in amplitude. Stim compromised [both]. Premature failure and replacement. | Output current check prior to starting a program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), | X |
| Current source transistor(s) fails as a short-circuit | More output current than programmed for that channel; possible net DC from channel. | Output current check prior to starting a program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Output capacitors stop high levels of DC current  (1310-000058) |  |
| Power source to Stim ASIC to be turned off when stimulation is off [SWSP 0112 req 544] |  |
| Hardware error with amplitude or phase register(s), correct data written to it | Incorrect pulse amplitude or incorrect phase order/timing. Patient would feel change in stimulation. Revision surgery required to replace IPG. | Output current check prior to starting a program |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), | X |
| Incorrect data written to amplitude or phase register(s) | Stimulation compromised, unintended or intermittent stimulation | Stim ASIC parity-check feature | Power glitch, cosmic rays, etc. | Data in Stim ASIC registers corrupted after program is running | 3 | 2 | 5 | 1 | 15 | 10 | Stim ASIC parity-check feature detects data corruption (SWSP 0112 req 609), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Data read-back after being written | Problem with the interface between the MSP430 and Stim ASIC | Incorrect or corrupt data written to registers | 3 | 2 | 4 | 2 | 24 | 20 | Data read-back prevents program from being started [swsp 0112 req 611, 612].  100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stimulation data check prior to starting a program | Stimulation data corrupted | 3 | 2 | 5 | 1 | 15 | 10 | Stimulation data check prevents corrupted program from being started [swsp 0112 req 599], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Output current check prior to starting a program | Firmware error causes incorrect data to be written | 3 | 2 | 5 | 1 | 15 | 10 | Output current check prevents corrupted program from being started [SWSP 0112 # 610, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Internal Reference | Provides references for stimulation output | External reference resistor open, shorted, or incorrect resistance | Incorrect output current (more or less than programmed). Patient would feel change in stimulation. Revision surgery required to replace IPG. |  |  | Random failure or defect | 3 | 2 | 2 | 2 | 12 | 8 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | X |
| Hardware error with the bandgap reference register | Incorrect output current (more or less than programmed). Patient would feel change in stimulation. Revision surgery required to replace IPG. |  |  | Random failure or defect | 3 | 3 | 2 | 1 | 6 | 6 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | X |
| Incorrect data in the bandgap reference register | Incorrect output current (more or less than programmed).  Patient would feel change in stimulation. Likely possible to program around this. |  | Power glitch, cosmic rays, etc. | Post-write data corruption | 2 | 2 | 2 | 1 | 4 | 4 | Trim value rewritten every time Stim ASIC is started up. [SWSP 0112 # 542], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | x |
| Hardware error with internal reference | Incorrect output current (more or less than programmed). Patient would feel change in stimulation. Revision surgery required to replace IPG. |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | X |
| Waveform DAC | Provides reference current for stimulation output | Hardware error with waveform DAC registers | Incorrect output current (more or less than programmed). Patient would feel change in stimulation. Revision surgery required to replace IPG |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | X |
| Incorrect data in waveform DAC registers | Incorrect output current (more or less than programmed). Patient would feel change in stimulation. Likely possible to program around this. | Parity error flag | Power glitch, cosmic rays, etc. | Post-write data corruption | 2 | 2 | 2 | 1 | 4 | 4 | Parity error alerts MSP430 to data corruption. Waveform DAC values rewritten every time (SWSP 0112 Req 609), Stim ASIC is started up during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Hardware error with waveform DAC | Incorrect output current (more or less than programmed).  Patient would feel change in stimulation. Revision surgery required to replace IPG |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | P100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detectionrequired | X |
| High Voltage Supply | Provides high voltage for stimulation | Failure of external components (inductor, diode, or power supply capacitors) | No stimulation current or less current than programmed due to low HV voltage. Patient would feel decrease in stimulation. Revision surgery required to replace IPG. | Check of the BCG bit in the BC\_CTRL1 register during power-up |  | Component failure | 3 | 2 | 2 | 2 | 12 | 8 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Hardware error with boost converter register(s) | No stimulation current or less current than programmed due to low HV voltage. Patient would feel decrease in stimulation. Revision surgery required to replace IPG. | Check of the BCG bit and/or data read-back |  | Random failure or defect | 3 | 2 | 4 | 1 | 12 | 8 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Incorrect data in boost converter register(s) | No stimulation current or less current than programmed due to low HV voltage. Patient would feel decrease in stimulation. Likely able to program around. |  | Power glitch, cosmic rays, etc. | Post-write data corruption | 2 | 2 | 4 | 1 | 8 | 8 | No immediate detection of error, but register will be re-written when a stimulation parameter (amplitude, PW, etc.) is changed [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Data read-back after writing | Problem with the interface between the MSP430 and Stim ASIC | Incorrect or corrupt data written to registers | 2 | 2 | 3 | 2 | 12 | 12 | Data read-back error forces stimulation to stop [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
|  | Firmware calculates incorrect HV supply setting | 2 | 2 | 4 | 1 | 8 | 8 | No immediate detection of error, but register will be re-written when a stimulation parameter (amplitude, PW, etc.) is changed [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim SPI interface | Allows data transfer between MSP430 and Stim ASIC | CS stuck asserted or de-asserted | MSP430 can’t read or write to STIM ASIC. Stimulation can’t be started. If stim is already active, can’t change parameters. Revision surgery required to replace IPG. | Data read-back after writing |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error could indicate this fault. Stim would not be allowed to start. [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Inadvertent assertion of CS | Possible incorrect data transfer. Stim may stop due to Stim ASIC errors. If problem persists, revision surgery may be required. | Stim ASIC error flags (WE, others?) |  | FW error, noise, or momentary short to another logic line | 2 | 2 | 3 | 1 | 9 | 6 | Stim ASIC errors force stimulation to stop [swsp 0112 609, 610], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CS line floating | Interrupted data transfer. If stim already active, can’t change parameters. Revision surgery required to replace IPG. | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error could indicate this fault. Stim would not be able to start. [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK stuck in one position (high or low) | No data transfer. Stimulation can’t be started. If stim is already active, can’t change parameters. Revision surgery required to replace IPG. | Data read-back after writing |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error could indicate this fault. Stim would not be able to start. [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK signal is irregular | Incorrect data transfer possible. Revision surgery possibly required to replace IPG. | Data read-back after writing |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error forces stimulation to stop [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CLK line floating | Incorrect data transfer. Revision surgery possibly required to replace IPG. | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error forces stimulation to stop [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| SDI or SDO stuck in one position (high or low) | Incorrect data transfer. Revision surgery possibly required to replace IPG. | Data read-back after writing |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error forces stimulation to stop [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| SDI or SDO line floating | Incorrect data transfer. Revision surgery possibly required to replace IPG. | Data read-back after writing |  | PCB trace or solder joint failure | 3 | 2 | 3 | 1 | 9 | 6 | Data read-back error forces stimulation to stop [swsp 0112 611, 612], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim ERR flag to MSP430 | Allows the Stim ASIC to alert the MSP430 that an error has been detected | ERR stuck high | No indication of an error condition on the Stim ASIC. If problem persists, patient won’t be able to start stimulation. | Pulse guard check at start of stimulation |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | Failure of the pulse guard check prevents program from being started [swsp 0112 req 0617, 0660, 0770], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| ERR stuck low | Continuous indication of an error condition on the Stim ASIC. If problem persists, no stimulation is possible. | Error indication that cannot be resolved |  | Random failure or defect | 3 | 2 | 3 | 1 | 9 | 6 | patient instructions for error displays on PoP or PPC (0300-000027), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| ERR line floating | No indication of actual error or false indication of error. If problem persists, stimulation would stop randomly. Also possible for stimulation to keep going under error condition(s)., though this would a double-fault. | Pulse guard check and error indications that cannot be resolved |  | PCB trace or solder joint failure | 3 | 2 | 4 | 1 | 12 | 8 | Failure of the pulse guard check prevents program from being started; unresolved error forces stimulation to stop [swsp 112 req 617, 660, 770], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim RUN input from MSP430 | Rising edge initiates the Stim ASIC’s internal sequencer | RUN stuck in one position (high or low) | Program cannot be initiated or, if timing controlled by MSP430, pulses cannot be executed. If problem persists, revision surgery is required. | Pulse guard check and/or stimulation output check at start of program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | Failure of pulse guard check or stimulation output check prevents program from being started [swsp 0112 req 617, 660, 770], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| RUN line floating | Program won’t start at edge transition (when commanded) and/or may start at a random time later. If problem persists, revision surgery is required. | Pulse guard check and/or stimulation output check at start of program |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Failure of pulse guard check or stimulation output check prevents program from being started [swsp 0112 req 944], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim STOP input from MSP430 | Stops stimulation at the end of a pulse phase if asserted | STOP stuck high prior to program starting | Only one phase of the program would run, then program would stop. Premature failure and replacement. | Stimulation output check at start of program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| STOP becomes stuck high during program or phase | Program will stop at end of phase, leaving rest of phases unexecuted Premature failure and replacement. | Background monitoring of program execution |  | Random failure or defect; firmware error | 3 | 2 | 2 | 1 | 6 | 4 | CONT line deasserting will stop stim anyway. [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| STOP stuck low | Unable to stop programs using STOP input. Program would eventually stop when supplies are shut down, but this would an uncontrolled stop. Premature failure and replacement |  |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | No additional detection required CONT line deasserting will stop stim. [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| STOP line floating | Floating input may cause inadvertent program stops; MSP430 would be unable to use STOP line. Premature failure and replacement | Background monitoring of program execution |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Pull-down resistor as close to Stim ASIC as possible to prevent random transitions  CONT line deasserting will stop stim. [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim SEL input from MSP430 | Selects which bank of phase registers is executed | SEL stuck in one position (high or low) at the start of a program | Chance of executing program from wrong set of phase registers; MSP430 could inadvertently write to active registers. Patient could receive unintended stimulation. If problem persists, revision surgery is required. | Stimulation output check at start of program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| SEL line floating | Floating input could cause inadvertent switching between banks at the start of a program cycle. Patient could receive unintended stimulation. If problem persists, revision surgery is required | Stimulation output check at start of program |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim CONT input from MSP430 | Determines whether Stim ASIC repeats program cycles | CONT stuck high while continuous stimulation mode being used | Unable to stop programs in a normal manner (by driving CONT low). Patient would receive unintended stimulation. Patient may feel a spike when stopping a program. | Patient response to over-stimulation.  Pulse guard tripped if CLK is stopped while CONT remains high |  | Random failure or defect | 3 | 2 | 4 | 1 | 12 | 8 | Pulse guard might trip if CONT remained high after CLK is stopped; swsp 0112 req 617, 660, 770], drive STOP input to ensure that stimulation ends after the last phase, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CONT stuck high while non-continuous stimulation mode being used | Potential for program cycle to begin immediately after previous cycle, which is equivalent to having a very high pulse rate; unable to stop programs in a normal manner. Patient would receive unintended stimulation. | Patient response to over-stimulation; pulse guard tripped if CLK is stopped while CONT remains high |  | Random failure or defect | 3 | 2 | 4 | 1 | 12 | 8 | Pulse guard would trip if CONT remained high after CLK is stopped; swsp 0112 req 617, 660, 770], drive STOP input to ensure that stimulation ends after the last phase, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CONT stuck low | IF CONT is being used, then program will stop at end of first cycle, causing understim. | Patient response to under-stimulation; use of SYNC to monitor continuous mode |  | Random failure or defect | 3 | 2 | 4 | 1 | 12 | 8 | When using continuous mode, use SYNC output [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| CONT line floating | Floating input could cause variable program frequency, causing either overstim or understim. | Patient response to over-/under-stimulation; use of SYNC to monitor continuous mode; pulse guard trips if CONT is high while CLK is stopped |  | PCB trace or solder joint failure | 3 | 2 | 4 | 1 | 12 | 8 | Pulse guard would trip if CONT remained high after CLK is stopped; swsp 0112 req 617, 660, 770], drive STOP input to ensure that stimulation ends after the last phase When using continuous mode, use SYNC output. [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim CLK input from MSP430 | Drives the time steps in each phase of a program | CLK stuck low or stuck high at start of a program | Unable to clock in other control lines, so stimulation never starts. Patient would not receive stimulation. Premature failure and replacement. | Stimulation output check at start of program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | CLK will be checked extensively during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| CLK stuck high or low during active stimulation phase | Pulse phase longer than desired. Patient would receive overstim for single pulse, then stimulation would stop. Patient can attempt to restart stim. Premature failure and replacement. | Pulse tripped if CLK stopped |  | Random failure or defect; FW error | 3 | 2 | 2 | 1 | 6 | 4 | Pulse guard would trip if CLK is stopped during a stimulation phase. [swsp 0112 req 617, 660, 770] CLK will be checked extensively during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| CLK stuck high or low during a delay | Delay lasts for an indefinite period of time; STOP may occur prior to completion of program cycle. Premature failure and replacement. | Only detectable if SYNC being used for timing feedback |  | Random failure or defect; FW error | 3 | 2 | 2 | 1 | 6 | 4 | Use of SYNC for timing feedback could alert MSP430 to CLK problem. [SWSP 0116], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) |  |
| CLK frequency too high | Pulses shorter than desired; also higher pulse rate if CONT asserted. Patient would receive stimulation that is different than what was requested. Premature failure and replacement. | Clock check diagnostic or SYNC feedback may detect problem |  | HW error in MSP430 oscillator; FW error | 3 | 2 | 3 | 1 | 9 | 6 | Gross clock errors could be detected by clock diagnostic [SWSP 0112 # 596] or SYNC feedback. CLK will be checked extensively during electrical test. [EEPR 0181], 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| CLK frequency too low | Pulses longer than desired; also lower pulse rate if CONT asserted. Patient would receive stimulation that is different than what was requested. Premature failure and replacement. | Pulse guard, clock check diagnostic or SYNC feedback may detect problem |  | HW error in MSP430 oscillator; FW error | 3 | 2 | 2 | 1 | 6 | 4 | Gross clock errors could be detected by clock diagnostic [SWSP 0112 # 596] or SYNC feedback. CLK will be checked extensively during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| CLK line floating | Floating could cause unpredictable clocking. Patient could possibly receive unpredictable stimulation. Premature failure and replacement. | Pulse guard, clock check diagnostic or SYNC feedback will detect problem |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Gross clock errors could be detected by clock diagnostic [SWSP 0112 # 596] or SYNC feedback. CLK will be checked extensively during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim RST input from MSP430 | Resets the Stim ASIC and puts all registers into a default state | RST stuck high (to DVDD\_STIM) | Unable to reset chip; unpredictable operation during power-up, power-down, and emergency reset conditions. Patient may receive brief unintended stimulation when starting or stopping a program. |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | Write safe values to all registers after RST deasserted for power-up and emergency conditions; write safe values to registers prior to asserting RST during power-down (EESP 0085), 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196),  No additional detection required | x |
| RST stuck low | Unable to communicate with Stim ASIC or get any handshaking feedback. Patient would not receive stimulation. | Failure of data read-back after writing to registers |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | Registers locked into default values while RST low (EESP 0085); MSP430 alerted to problem when data read-back fails. RST will be checked extensively during 100 % electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| RST accidentally asserted by FW | All stimulation output stops; all registers back to default. Patient would detect stim stopping and would be able to restart. | SYNC feedback would detect lack of stimulation output |  | FW error | 2 | 2 | 4 | 1 | 8 | 8 | IPG will require patient to re-start program, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| RST line floating | Floating could cause random assertion of RST during stimulation | SYNC feedback would detect lack of stimulation output |  | PCB trace or solder joint failure | 3 | 2 | 4 | 1 | 12 | 8 | Pull-down resistor as close as possible to Stim ASIC input to prevent random behavior; this would force Stim ASIC to be permanently disabled if RST trace problem occurs (1330-000054). RST will be checked extensively during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim power DVDD\_STIM | Digital power from Power ASIC for Stim ASIC digital | DVDD\_STIM stuck on | Unable to turn off Stim ASIC; higher DVDD current during Idle mode. Impact would be shorter battery run time. |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | DVDD\_STIM to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | X |
| DVDD\_STIM stuck off (includes no-connect) | Unable to correctly power-up Stim ASIC; MSP430 could parasitically power Stim ASIC through logic lines. Premature failure/replacement |  |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | DVDD\_STIM to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | X |
| Stim power AVDD | Analog power from Power ASIC to Stim ASIC analog | AVDD stuck on | AVDD powered up while DVDD\_STIM is off. Battery life impact |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | No additional detection required. AVDD to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| AVDD stuck off (includes no-connect) | Reference voltages and currents would not be generated, so no output from Stim ASIC. Stimulation cannot be started by patient. Premature fail/replace |  |  | Random failure or defect;  FW error | 3 | 2 | 2 | 1 | 6 | 4 | No additional detection required. AVDD to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim PROG output to MSP430 | Indicates that the Stim ASIC is running a program. | PROG stuck high | MSP430 thinks a program is running at all times. Long term consequence is explant due to underestimation. | Check for proper operation of PROG before starting program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| PROG stuck low | MSP430 thinks a program is not running even when it is. Long term consequence is explant due to underestimation. | Check for proper operation of PROG before starting program |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| PROG line floating | Floating causes incorrect feedback to MSP430. Long term consequence is explant due to underestimation. | Check for proper operation of PROG before starting program |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim SYNC output to MSP430 | Indicates certain phase transitions if enabled | SYNC line stuck on, stuck off, or floating | If SYNC being used, could cause incorrect feedback to MSP430. | Check for proper operation of SYNC before starting program |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim PAUSE output to MSP430 | Indicates that the Stim ASIC is paused | PAUSE line stuck on, stuck off, or floating | If PAUSE being used, could cause incorrect feedback to MSP430. Premature failure/replacement. | Check for proper operation of PAUSE before starting program |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim TFLG output to MSP430 | Indicates that sample-and-hold timer has tripped | TFLG line stuck high or low | MSP430 won’t detect timing information from S/H. Premature failure/replacement. | Check for proper operation of TFLG before measuring impedance |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| TFLG line floating | Floating causes incorrect sample indication to MSP430. Premature failure/replacement. | Check for proper operation of TFLG before measuring impedance |  | PCB trace or solder joint failure | 3 | 2 | 2 | 1 | 6 | 4 | Functionality of PCB to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Stim IMPM\_OUT output to MSP430 | Provides analog output for measurement of impedance between two channels. | IMPM\_OUT line stuck high, stuck low, or floating | Incorrect impedance voltage appears at MSP430. Possible inadvertent disabling of programs – revision surgery likely. | Check for proper operation of impedance measurement circuit before use |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 1 | 1 | 3 | 2 | Check impedance circuit prior to making measurement by connecting reference voltages to IMPM\_OUT. [SWSP 0112 #913], IMPM\_OUT to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Impedance measurements amps not working correctly | Incorrect impedance voltage. Possible inadvertent disabling of programs – revision surgery likely. | Check for proper operation of impedance measurement circuit before use |  | Random failure or defect | 3 | 2 | 1 | 1 | 3 | 2 | Check impedance circuit prior to making measurement by connecting reference voltages to IMPM\_OUT. [SWSP 0112 #913], IMPM\_OUT to be checked during 00% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Stim CALP\_RESIN & CAL\_RESOUT lines | Provides analog output for measuring current source and sink amplitudes | CALP\_RESIN and/or CAL\_RESOUT lines stuck high, stuck low, or floating | Incorrect current output measurements. Patient would be unable to start stimulation. Revision surgery likely. | Check for proper operation of amplitude calibration circuit before use |  | Random failure or defect; PCB trace or solder joint failure | 3 | 2 | 1 | 1 | 3 | 2 | Calibration circuit to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| Calibration resistor failure | Incorrect current output measurements. Patient would be unable to start stimulation. Revision surgery likely. | Check for proper operation of amplitude calibration circuit before use |  | Random failure or defect; solder joint failure | 3 | 2 | 1 | 1 | 3 | 2 | Calibration circuit to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |
| Calibration amps not working correctly | Incorrect current output measurements. Patient would be unable to start stimulation. Revision surgery likely. | Check for proper operation of amplitude calibration circuit before use |  | Random failure or defect | 3 | 2 | 1 | 1 | 3 | 2 | Calibration circuit to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| HVDD\_CONN input from MSP430 | Enables high voltage supply connection to the channels | HVDD\_CONN line stuck high | Channels cannot be immediately disconnected from HVDD, potentially powering channels while rest of chip is off; possible unintended output current spike during power-down. Patient could possibly feel spike when stim is turned off. (Revision unlikely) | Patient might feel spike when stim is turned off. |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | Patient may feel spike when stim is turned off. HVDD\_CONN to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| HVDD\_CONN line stuck low | Power cannot be applied to output channels; device can no longer provide stimulation. Revision surgery required. | Stimulation output check at start of program |  | Random failure or defect | 3 | 2 | 1 | 1 | 3 | 2 | Failure of the output check prevents programs from being started, disabling the IPG. HVDD\_CONN to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| HVDD\_CONN line floating | Floating could cause random application of power to output channels. Patient would feel intermittent stim. Revision surgery required. | Stimulation output check at start of program might catch problem. |  | PCB trace or solder joint failure | 3 | 2 | 3 | 1 | 9 | 6 | Failure of the output check prevents programs from being started, though this might be caught every time. HVDD\_CONN to be checked during 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| QSO Switch | Turns stimulation off | Switch fails open or closed | Can’t turn stim off quickly from button. Overstim no surgery required, patient discomfort | Patient observes button does not work |  | switch component failure or mechanical obstruction | N/A | 2 | 5 | 2 | N/A | 20 | PoP QSO [EESP 0097], statement to disconnect trial cable in manual (0300-000028), EPG battery removable [EESP 0091], 100% electrical test in manufacturing (EEPR 0196) | x |
| Magnetic Switch | Provides magnetic switch input to microcontroller for 2 second presence stim on/off ( 5 second power off covered in power section) | Stuck in “open” state |  | Detect non-latent failures during manufacture.  Patient observation during in-field latent failure |  | Random component failure or defect, likely at time of manufacture | 2 | N/A | 3 | 1 | 6 | N/A | Part selection (1330-000054), system integration testing (QARE 0544) , other means of stim on/off including PoP and PPC, 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | x |
| Stim LED | Indicates stimulation | Fails off | Misleading, inconvenience | Patient may notice device is stimulating and light not blinking, Light doesn’t flash during trial stim |  | LED burns out | N/A | 2 | 3 | 1 | N/A | 6 | LED selection [1100-000179] |  |
|  |  | Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0195, EEPR 0196) | x |
| Fails On | Misleading, inconvenience | Patient may notice device is not stimulating &light is on |  | Microcontroller failure or board short | N/A | 2 | 3 | 1 | N/A | 6 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | x |

## Protection Circuitry

| **IPG 2412/2408**  **EPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Protection Circuitry**  Output Capacitors | Charge balance the current output | Sudden short after an extended period of time | Loss of charge balance control during stimulation. Electrode corrosion possible. |  |  | Component failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Decrease in capacitance over time | No effect |  |  | Component aging | 1 | 1 | 5 | 1 | 5 | 5 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required | x |
| Increase in capacitor leakage current over time | Increase in leakage current to patient. Tissue damage and electrode corrosion possible. |  |  | Component aging | 3 | 2 | 5 | 2 | 30 | 20 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection or mitigation required | x |
| Protection Diodes | Protection of IPG channels from defibrillation pulses, electrocautery, and ESD | TVS shorted to common node | For affected channel, output current could be directed into IPG’s ground instead of going out to electrode. Channel would be lost, affecting stim felt by patient. | Change in the feeling of stimulation. |  | One or more exposures of IPG to high energy event such as ESD, cautery, or cardiac defibrillation | 3 | 2 | 5 | 2 | 30 | 20 | DVT for defibrillation, electrocautery  [EESP 0071 F86, F89, EERE 0545] |  |
| TVS opened by over-voltage event, leading to damaged output channel | Loss of output channel, affecting stim felt by patient. | Change in the feeling of stimulation. |  | One or more exposures of IPG to high energy event such as ESD, cautery, or cardiac defibrillation | 3 | 2 | 2 | 2 | 12 | 8 | DVT for defibrillation, electrocautery,  [EESP 0071 F86, F89, EERE 0545]  Stimulation output check prevents program with damaged channel from being started [SWSP 0112] |  |
| Increase in TVS leakage current over time | Increase in leakage current to patient. Electrode corrosion possible. |  |  | One or more exposures of IPG to high energy event such as ESD, cautery, or cardiac defibrillation | 3 | 2 | 5 | 2 | 30 | 20 | No additional detection required. DVT for defibrillation, electrocautery[EESP 0071 F86, F89, EERE 0545] |  |
| Component aging | 3 | 2 | 5 | 2 | 30 | 20 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | x |

## MICS Radio Subsystem

| **IPG 2412/2408**  **EPG 4300** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S**  **[IPG]** | **S**  **[EPG]** | **D** | **O** | **RPN**  **[IPG]** | **RPN**  **[EPG]** | **Mitigation Action** | **Mfg.** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| IPG Antenna, feedthroughs, and flex fingers | Provides RF link to external programming devices | Antenna or flex fingers become open or short-circuit permanently or intermittently | Loss of MICS communications. Patient would permanently or intermittently lose ability to adjust stim. | Patient would notice poor performance of link. |  | Random failure of antenna in header; solder joint failure; flex finger cycle fatigue | 3 | N/A | 4 | 2 | 24 | N/A | If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926]; flex finger traces designed as wide as possible; 1320-000054 (layout)flex finger polyimide layers as thin as possible with trace centered between them (1330-000054 Assembly Drawing), MICS to be checked extensively during electrical production test as well as electrical and mechanical DVT. [EEPR 0181, EEPR 0182, QAPR 0135, MERE 0440, QARE 0544] | X |
| IPG flipped so that antenna faces inward | Reduced MICS range. | Patient would notice redused MICS range. |  | Doctor error or patient fiddling with IPG | 2 | N/A | 3 | 3 | 18 | N/A | Ability to maintain MICS communications, but at a reduced range; DVT characterization of MICS link when IPG flipped.[QAPR 0135, QARE 0544] |  |
| Change in shape / mechanical distortion | Change in antenna gain, resulting in lost range | If during manufacturing, final functional test would catch this. If after implant, patient would notice decreased range. |  | Mechanical shock to the IPG or manufacturing error. | 2 | N/A | 2 | 1 | 4 | N/A | Final electrical test will catch manufacturing defects. [EEPR 0182] If stimulation is active when MICS communications lost, ability to turn off IPG using magnet. [EESP 0071 F5926] |  |
| Fluid ingress into changes antenna tuning; detuned from factory settings | Antenna becomes detuned and MICS range decreases. | Patient may notice decreased MICS range over time. |  | Fluid ingress into header over time. | 2 | N/A | 3 | 5 | 30 | N/A | Ability for antenna to be retuned on demand.  [EESP 0071 F2754-f ] |  |
| EPG Antenna (traces on board) | Provides RF link to external programming devices | Antenna becomes open or short-circuit permanently or intermittently | Loss of MICS communications. Patient would permanently or intermittently lose ability to adjust stim. | Patient would notice poor performance of link. |  | Open or short of antenna to PC board | N/A | 2 | 3 | 1 | N/A | 6 | If stimulation is active when MICS communications lost, ability to turn off EPG using QSO or unplug screening cable [EESP 0091 F6456, F4053].  100% electrical test in manufacturing [EEPR 0196] | X |
| Antenna matching network | Provides impedance matching for antenna | Network short, open, or component failure | Loss of MICS or reduced range | If during manufacturing, electrical test would catch this. If after implant, patient would notice decreased range or complete loss of MICS. |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] | X |
| MICS crystal | Provides timing source for the MICS radio | Crystal fails open, short, or floating | Loss of MICS | MICS chip returns error if clock problem detected on startup. Patient would detect loss of MICS. |  | Random failure or defect | 3 | 2 | 2 | 1 | 6 | 4 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| Crystal frequency incorrect due to drift over time | Loss of MICS or reduced performance | MICS chip returns error if clock problem detected on startup. Patient would detect reduced MICS range. |  | Random failure or defect;  Crystal aging | 3 | 2 | 3 | 1 | 9 | 6 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | x |
| MICS SPI interface | Allows data transfer between MSP430 and MICS chip | CS stuck asserted or de-asserted | MSP430 can’t read or write to MICS chip; MICS communications lost. Revision surgery required to replace IPG. | Data read-back after writing. Patient would detect loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926], and EPG using QSO button (EESP 0091) | xX |
| Inadvertent assertion of CS | Possible incorrect data transfer; MICS communications possibly lost. If problem persists, revision surgery may be required. | Patient detects decrease in MICS performance. |  | FW error or noise | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), MICS data corruption detection diagnostic may catch data errors (ZL70102 Design Manual Revision: 1.0 January 2011). | x |
| CS line floating | Interrupted data transfer; MICS communications intermittently lost. If problem persists, revision surgery may be required. | Data read-back after writing. Patient detects decrease in MICS performance. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196),] If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| CLK stuck in one position (high or low) | No data transfer; MICS communications lost. | Data read-back after writing. Patient detects loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| CLK signal is irregular | Incorrect data transfer; MICS communications lost. | Data read-back after writing. Patient detects loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196),] If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| CLK line floating | Incorrect data transfer; MICS communications lost | Data read-back after writing. Patient detects loss of MICS. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| SDI or SDO stuck in one position (high or low) | Incorrect data transfer; MICS communications lost | Data read-back after writing. Patient detects loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| SDI or SDO line floating | Incorrect data transfer; MICS communications lost | Data read-back after writing. Patient detects loss of MICS. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| MICS IRQ output to MSP430 | Interrupts MSP430 during wakeup, data transfer, and other various functions | IRQ line stuck high or low | MSP430 gets no interrupt from MICS chip, so loss of MICS communications. | Patient detects loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| IRQ line floating | Floating may cause random interrupts; real interrupts will not get through. Loss of MICS communications. | Patient detects loss of MICS. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| MICS WU\_EN input from Power ASIC | Triggers the initialization of the MICS radio and acts as input strobe for checking wakeup | WU\_EN input stuck high | Radio powered up at all times; could drag down DVDD supply and cause a POR. If stimulation active, it will turn off during the POR. PORs could happen continuously. loss of MICS communications. | Patient detects loss of stimulation and loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196) | X |
| WU\_EN input stuck low | Radio powered down at all times; loss of MICS communications. | Patient detects loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| WU\_EN input floating | Floating may cause random wakeups; intended wakeups can’t get through; loss of MICS communications; DVDD pulled down to cause a POR. | Patient detects loss of stimulation and loss of MICS. |  | PCB trace or solder joint failure | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| MICS power DVDD\_MICS | Digital power from Power ASIC for MICS radio | DVDD\_MICS stuck on | Unable to totally power-down MICS radio; DVDD\_MICS will usually be powered up at all times anyway. Reduced battery life |  |  | Random failure or defect | 2 | 2 | 5 | 1 | 10 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), No additional detection required. | X |
| DVDD\_MICS stuck off (includes no-connect) | Unable to power-up MICS radio; loss of MICS communications; parasitic powering may make difficult to detect. Unable to communicate | Patient detects complete or partial loss of MICS. |  | Random failure or defect | 3 | 2 | 5 | 1 | 15 | 10 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182, EEPR 0195, EEPR 0196), If stimulation is active when MICS communications lost, ability to turn off IPG using magnet [EESP 0071 F5926] and EPG using QSO button (EESP 0091) | X |
| MICS radio registers | Detects data corruption in MICS radio backup registers | MICS radio detects CRC error | Chip setup could be incorrect, reduced RF performance | MICS radio can interrupt processor |  | Post-write data corruption | 2 | 1 | 5 | 1 | 10 | 5 | Requirement for MSP430 to detect MICS CRC errors [SWSP 0112 #991, 994, ] and rewrite backup registers if necessary |  |

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Level** | **Revision Description** | **ECN**  **No#** | **Effective Date** |
| 1.1 | * Initial FMEA against IPG specification EESP 0071 rev 1.2. * This revision is an interim analysis, which will be updated to address the open items listed in section 8. | 1561 | 10/16/12 |
| 1.2 | * Aligned excessive heat with EEEX 0071 * Updated references to functional specifications, drawings, software design spec, and test protocol * Updated mitigations to reference protocols and specs where applicable * Updated mitigations to match functional specs (SWSP 0112 rev 1.5 and EESP 0071 rev 1.5) * Reduced severity on Vbat-f short circuit for IPG based on MERE 0331 | 1930 | 09/17/13 |
| 1.3 | * Added reference documents to mitigation actions where applicable. * Updated mitigation items with additional details and updates. * Updated occurrence of IPG antenna open/short * Addressed open items listed in section 10. | 2163 | 12/23/13 |

1. Detailed interfaces between the microcontroller and the Stim, Power, and RF sections are covered in their respective sections. [↑](#footnote-ref-1)