# Background, Purpose & Scope

The purpose of this assessment is to provide a fault tree analysis of the implantable neurostimulator system (INS).

**Model Name Model Number**

Implantable Pulse Generators (IPGs) Kits

2-bore, 12 contact 2412

3-bore, 8 contact 2408

Lead Kits

Percutaneous

8-Electrode 1081-45, 1081-60, 1081-75, 1081-90

1084-45, 1084-60, 1084-75, 1084-90

1086-45, 1086-60, 1086-75, 1086-90

12-Electrode 1121-45, 1121-60, 1121-75, 1121-90

1124-45, 1124-60, 1124-75, 1124-90

1126-45, 1126-60, 1126-75, 1126-90

8-Electrode Trial 1081-45T, 1081-60T, 1084-45T, 1084-60T

12-Electrode Trial 1121-45T, 1121-60T 1124-45T, 1124-60T

Surgical

3, 4, 3, 2-Electrode 3000-45, 3000-60

2x6-Electrode 3101-45, 3101-60

Extension Kits

8-Electrode 5208-20, 5208-40, 5208-60

12-Electrode 5212-20, 5212-40, 5212-60

Accessories

Trail Cable and Lead Kit 5000

Tunneling Tool Kits

Standard 5100

Long 5110

Introducer Needle

4 inch 5300

6 inch 5310

Mechanical Anchor 5400

Adhesive Anchor 5410

Port plug 5510

Magnet 4900

Torque Wrench 5500

Passing Elevator Kit 5600

Allergy Kit 5700

External Devices

Patient System Kit 4000

Programmer Power Cord 4010

Patient System Case 4020

Pocket Programmer (PoP) 4100

Patient Programmer Charger (PPC) Kit 4200

Adjustable Belt 4220

Charging Paddle 4230

Adhesive Patches 4240

External Pulse Stimulator (EPG) / Trial Stimulator 4300

Trial Stimulator Pouch 4320

Clinician Programmer (CP) Kit 4500

Patient Feedback Tool 4520

Clinician Programmer Printer 4530

Clinician Programmer Printer Paper 4540

Field System Case 4550

Magnet 4900

This is one of three types of analysis for this system as described in EEPL 0042 IPG System Risk Management Plan, the others being a preliminary hazard analysis (PHA) and failure mode effects analysis (FMEA).

This document is revised throughout the development process to reflect progress in controlling and assessing risk.

# References

## Internal Plans, Procedures, and Specifications

* Risk Documentation
  + EEEX 0071 SCS Hazard Summary
  + EEPL 0042 IPG System Risk Management Plan
  + QAQP 0061 Risk Management procedure
  + QARE 0141 SCS System Software Risk Analysis
  + QARE 0137 Preliminary Hazard Analysis Report
  + QARE 0222 SCS System Usability Risk Assessment
  + MERE 0146 IPG and Leads Toxicology Report
  + MERE 0170 Battery Related Risk Findings
  + MERE 0331 Battery Short Circuit Testing
  + QARE 0512 Wireless Interface Risk Assessment
  + 1013760 Greatbatch Medical Endotoxin Test Report
  + SWEX 0185 Algostim Known Anomalies List
* Specifications
  + MKSP 0069 24-Channel Implantable Pulse Generator System Marketing Specification
  + MKSP 0081 8 electrode Percutaneous Lead Marketing Specification
  + EESP 0071 IPG Functional Specification
  + SWSP 0072 Patient Programmer Functional Specification
  + SWSP 0073 Clinician Programmer Functional Specification
* Design FMEA
  + MEFM 0021 IPG Mechanical Design FMEA
  + EEFM 0022 IPG Electrical Design FMEA
  + SWFM 0025 IPG Software Design FMEA
  + MEFM 0019 8 and 12 Conductor Percutaneous Lead Design FMEA
  + MEFM 0020 8 and 12 Conductor Surgical Lead Design FMEA
  + 2993 DFMEA (Battery -Alden GBM Documentation System)
  + 2714 FFT DFMEA and 2737 FFT DFMEA (Feedthrough -10K Documentation System)
  + DP-0002-23-8 PoP System FMECA
  + DP-0002-23-9 PPC System FMECA
  + DP-0002-24-1 PoP Software FMECA
  + DP-0002-24-6 PPC Software FMECA
* Process FMEA
  + 1004467 QiG Header Assembly PFMEA (Plymouth GBM Documentation System)
  + 1005682 Percutaneous Lead PFMEA (Plymouth GBM Documentation System)
  + 1005684 SCS Surgical Lead PFMEA (Plymouth GBM Documentation System)
  + 1005688 SCS Extension Lead PFMEA (Plymouth GBM Documentation System)
  + PFMEA Li Ion Mixing and Coating, Li Ion Rolling and Slitting, Li Ion Assembly (Battery - Alden GBM PFMEA Software)

## Risk Analysis Meeting Minutes

* 20090414 Stimulation Hazards #1 (Overstimulation)
* 20090415 Stimulation Hazards #2 (Under stimulation, Charge Density, Leakage)
* 20090415 Recharging Hazards (Heat & EMI)
* 20090513 Stimulation Hazards (Lead System)
* 20090617 Charge and Current Density
* 20090709 EPG Risk Analysis
* 20090709 External Device Risk Review (Focused on patient programmer-charger and Pocket Programmer)
* 20090722 Charge Imbalance and DC Leakage (net DC)
* 20091001 IEC 62304 Risk Input Review
* 20091001 Physician discussion on IPG System and Procedure Hazards Clinician reviews
* 20091002 Software Interface Review
* 20091008 Minnetronix Risk Review of FTAs
* 20091014 CP, IPG, & EPG feature review of risk assessment
* 20091015 PPC & PoP feature review of risk assessment
* 20091109 EPG and Magnet feature review of risk assessment
* 20091109 Project Design Review (Risk Status Presented and Reviewed by Management)
* 20091110 CP feature review of risk assessment
* 20091112 Clinician inputs to system risk (Slavin)
* 20091116 Environmental Damage
* 20091116 Erosion hazard review
* 20091125 Lead System Review - Lead, Anchor, Needles, Packaging, IPG-Lead interconnect
* 20091221 Lead System Review - Lead, Anchor, Needles, Packaging, IPG-Lead interconnect (continued)
* 20100201 Lead System Review - Lead, Anchor, Needles, Packaging, IPG-Lead interconnect (continued)
* 20100423 IPG Electrical and Firmware Risk Mitigation Discussion
* 20100524 General cleanup call
* 20100722 Lead Introducer Needle Process and associated Hazard Review
* 20100804 Meeting minute review and results of traceability activity
* 20120801 Three Bore IPG
* 20120813 Elevator & Lead Blank
* 20130604 Clinician Review of Hazards

## Standards

* EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices
* IEC 61025:2006 Fault Tree Analysis (FTA)
* IEC 62304:2006 Medical device software – Software life cycle processes

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# Risk Analysis Summary

Risk management activities for this project were undertaken per EEPL 0042 IPG System Risk Management Plan and QAQP 0061 Risk Management Procedure.

The overall residual risk level was reduced to As Low as Reasonably Practicable (ALARP) or Broadly Acceptable regions and Risk/Benefit is not required. The system identified in this report meets risk management criteria and will be considered acceptable for use.

Appropriate methods will be in place to monitor and obtain relevant production and post-production information. Additional details of the risk assessment are documented in the risk management file.

## Software Classification

The Software classification was determined to be B (per IEC 62304:2006) and a moderate level of concern (per FDA guidance document) for all software systems as described in QARE 0141 SCS System Software Risk Analysis. The risk of serious injury or death from software failure is reduced to acceptable levels by several redundant hardware controls such as ‘off button’ and magnet mode. There is no reasonable probability that a software issue will cause death or serious injury, as the loss of functionality for pain stimulation systems does not present a reasonable probability of death or serious injury.

Risk-based software controls are identified as ITEMs in the software documentation.

Known software anomalies are documented in SWEX 0185 Algostim Known Anomalies List and have been evaluated and deemed acceptable in a final product release based on the probability that a customer will encounter the anomaly and the severity of the behavior of the device when the anomaly is encountered.

# Review History

* Any reviewer who has attended at least one discussion is included under names.
* Most hazards have had multiple review dates.
* Only reviews are included in this table. Initial discussions (20090414 and 20090415) are not listed.
* Minutes from each review may be found in risk management file.

## Review of Device Related Risks

Table 1 - Review of Device-Related Risks

| **Topic** | **Reviewer(s)** | **Date** |
| --- | --- | --- |
| Under stimulation   * Non Surgical Correction * Surgical Correction Required | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  John Swoyer (Director Product Development)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Dave Howard (Senior Engineer)  Dan Kelsch (Engineering Program Manager) Mechanical  Bob Zenz (Quality Engineering)  Konstantin Slavin, MD (Consultant)  Richard North, MD (Consultant) | 20090513  20090709  20091108  20091112  20100423  20100524  20120607 |
| Allergen Exposure | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  John Swoyer (Director Product Development)  Salim Hayek, MD (Consultant)  Konstantin Slavin, MD (Consultant) | 20090513  20091001  20091112 |
| Bio-incompatibility and Bio-instability | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  John Swoyer (Director Product Development) | 20090513 |
| CSF Leak | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant) | 20091001 |
| Environmental Damage | Ben Cottrill (Project Manager)  Carole Norris (Packaging Engineering Consultant)  Bernie Bosley (Risk Management Consultant) | 20091116 |
| Erosion | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  John Swoyer (Director Product Development)  Bob Zenz (Quality Engineering)  Konstantin Slavin, MD (Consultant)  Richard North, MD (Consultant) | 20090513  20091116  20091112  20120607 |
| Excessive Heat | Bernie Bosley (Risk management consultant)  Ben Cottrill (Project Manager)  Roger Fell (Senior Engineer)  Mike Labbe (Director)  Rich Polefko (Sr. Electrical Engineer)  Alex Smith (Senior Project Engineer)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Steve Wilder (Engineering Program Manager) Software  Bob Zenz (Quality Assurance Manager) | 20090709 |
| Excessive Heat – Severe | Bernie Bosley (Risk management consultant)  Ben Cottrill (Project Manager)  Roger Fell (Senior Engineer)  Mike Labbe (Director)  Rich Polefko (Sr. Electrical Engineer)  Alex Smith (Senior Project Engineer)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Steve Wilder (Engineering Program Manager) Software  Bob Zenz (Quality Assurance Manager) | 20090709 |
| Infection | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Dave Howard (Senior Engineer)  Bob Zenz (Quality Engineering)  Konstantin Slavin, MD (Consultant)  Richard North, MD (Consultant) | 20091001  20091109  20091110  20091112 |
| Infection of Central Nervous System or Spinal Canal | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant) | 20091001 |
| Misleading Information | Bernie Bosley (Risk management consultant)  Ben Cottrill (Project Manager)  Mike Labbe (Director)  Steve Wilder (Engineering Program Manager) Software  Bob Zenz (Quality Assurance Manager)  Scott Leyh (Senior Software Engineer)  Rich Polefko (Sr. Electrical Engineer)  Steve Wilder (Engineering Program Manager) Software | 20091001  20091110 |
| Neural Compression or Damage | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Richard North, MD (Consultant) | 20091001  20120607  20120607 |
| Overstimulation   * Non Permanent & Non-Surgical Correction * Overstimulation – Surgical Correction | Ben Cottrill (Project Manager)  Bob Zenz (Quality Assurance Manager)  Jeff Weisgarber (Engineering Program Manager) Electrical  Stephen Trier (Senior Engineer)  Scott Leyh (Senior Software Engineer)  Bernie Bosley (Risk management consultant)  Rich Polefko (Sr. Electrical Engineer)  Alex Smith (Senior Project Engineer)  Steve Wilder (Engineering Program Manager) Software  Dave Howard (Senior Engineer)  Dan Kelsch (Engineering Program Manager) Mechanical | 20090519 20090529  20090709  20100423  20100524 |
| Charge Imbalance and DC Leakage | Bernie Bosley (Risk management consultant)  Ben Cottrill (Project Manager)  Mike Labbe (Director)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Dave Howard (Senior Engineer)  Steve Wilder (Engineering Program Manager) Software  Bob Zenz (Quality Assurance Manager) | 20090722 |
| Excess Charge Density or Current Density | Jeff Weisgarber (Engineering Program Manager) Electrical  Stephen Trier (Senior Engineer)  Rich Polefko (Senior Software Engineer)  Ben Cottrill (Project Manager)  Bob Zenz (Quality Assurance Manager)  Mike Labbe (Director)  Bernie Bosley (Risk management consultant)  John Swoyer (Director, Product Development)  Jesse Geroy (Manager, R&D)  Richard North, MD (Consultant) | 20090617  20120607 |
| Toxicity | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant) | 20091001 |
| Trauma | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant) | 20091001 |
| Electrical Shock | Bernie Bosley (Risk management consultant)  Ben Cottrill (Project Manager)  Roger Fell (Senior Engineer)  Mike Labbe (Director)  Rich Polefko (Sr. Electrical Engineer)  Alex Smith (Senior Project Engineer)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Steve Wilder (Engineering Program Manager) Software  Bob Zenz (Quality Assurance Manager) | 20090709 |
| Unintended Effect | Bernie Bosley (Risk Management Consultant)  Ben Cottrill (Project Manager)  John Swoyer (Director Product Development)  Stephen Trier (Senior Engineer)  Jeff Weisgarber (Engineering Program Manager) Electrical  Dave Howard (Senior Engineer)  Bob Zenz (Quality Engineering) | 20090513  20091109 |
| Unintended Revision Surgery | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |

## Review of Procedure Related Risks

Table 2 - Review of Procedure-Related Risks

| **Topic** | **Reviewer(s)** | **Date** |
| --- | --- | --- |
| Edema & Seroma | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |
| Infection | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant)  Konstantin Slavin, MD (Consultant) | 20091001  20091112 |
| Infection of Central Nervous System or Spinal Canal | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |
| Trauma | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |
| Unintended Revision Surgery | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |
| Bio-incompatibility | Ben Cottrill (Project Manager)  Salim Hayek, MD (Consultant)  Bernie Bosley (Risk Management Consultant) | 20091001 |
| All hazards | Paul Battle (Clinician)  Bernie Bosley (Risk Management Consultant)  Kathy Jo Fahey (Clinical / Regulatory)  Stacy Skare (Clinical / Regulatory) | 20130604 |

# System Intended Use

The system is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain.

## Implantable and External Pulse Generators

The Implantable and External Pulse Generator (IPG/EPG) generates electrical pulses for delivery to a target stimulation site via a lead. The EPG will be connected to the lead via a percutaneous extension or screening cable. The EPG has the same stimulation capabilities as the IPG, with the exception of the active enclosure, which may be replaced with a patch or other electrode. The EPG is a non-sterile external use device for intra-operative or sub-chronic post-surgical stimulation.

## Clinician Programmer

The Clinician Programmer (CP) is used by the clinician to program the patient’s IPG and/or EPG. The Clinician Programmer supports the Clinician Application by allowing the clinician to communicate with an IPG and/or EPG and OS supported printers.

## Pocket Programmer

The Pocket Programmer (PoP) is used by the Patient to adjust his/her stimulation therapy as provided by the IPG and/or EPG. It can control amplitude, program choice, and stimulation on/off.

## Patient Programmer Charger

The Patient Programmer Charger (PPC) is a take-home device that is used for more advanced stimulation control functionality (e.g. frequency, pulse width, amplitude of individual pulses), diagnostics (impedance checks), and maintenance (charging).  The PPC includes a main control unit (portable battery pack with control circuitry) that is used by the Patient to adjust his/her IPG and/or EPG therapy and to initiate recharging the IPG battery as well as a coil that is connected via a cable.   This coil is inductively coupled to the IPG charging circuitry for power transfer and communications.

As heat is the primary hazard for this device, least favorable conditions exist in two areas:

1. Situations where the device is insulated from cooling such as if recharge coil is covered by heavy blankets or trapped between patient and soft cushion of a chair
2. Line power is higher than stated voltage

## Patient Feedback Tool

The Patient Feedback Tool (PFT) is used by the patient to deliver stimulation feedback to the clinician and sales representative during programming. This device communicates only with the Clinician Programmer.

# Essential Performance

## Essential Performance requirements

Essential Performance requirements address safety and freedom of unacceptable risks. Risk assessment determines Essential Performance and safety that must be examined during specific safety testing. The criterion applies to all functions of the equipment. Essential Performance includes patient safety, clinician safety, product performance, and transportation / storage.

During single fault and immunity testing (required by EN60601-1 and EN60601-1-2) each function of the equipment / system that is associated with Essential Performance shall be tested in the mode that is most critical from a patient outcome perspective (using equipment options, cable layout, and accessories in typical configuration) consistent with normal use.

This system is intended for spinal cord stimulation for the treatment of chronic, intractable pain of the trunk and/or limbs. It is not a life-sustaining or life supporting system. Essential Performance is performance essential to the safety of the patient, without which, may cause harm to the patient. Absence of therapy (stimulation) does not meet the requirements for Essential Performance since the patient is in no harm due to its’ absence.

For the purpose of defining essential performance, the SCS system is defined as either of two configurations

1. Trial stimulation configuration consists of:
   1. CP
   2. EPG
   3. Connection cable and leads
   4. PoP
   5. PFT
2. Long term implant configuration consists of:
   1. CP
   2. PoP
   3. PPC
   4. Leads
   5. IPG
   6. PFT

Essential performance of either system configuration described above is defined as:

* Maintain ability to turn stimulation off by at least one of several means. The patient or clinician shall have access to at least one redundant means of turning stimulation off. Examples include:
  + Clinician programmer ‘stim off’ function accessible on all screens
  + Standalone magnet
  + Patient Programmer Charger ‘stim off’ function via 2 separate communication means
  + Pocket Programmer ‘stim off’ function
  + Simple unplug of trial stimulation cable
* Pulse output (amplitude frequency and pulse width) during and after test does not increase by more than 10% from the clinician set maximum limits.

Thus on a per-device basis, the essential performance is:

* PoP: No essential performance, since the PoP cannot cause xPG to exceed pre-set clinician limits (it can only request an increase, xPG decides whether to execute request based on limits set by the CP)
* PPC: No essential performance, since the PPC cannot cause xPG to exceed pre-set clinician limits (it can only request an increase, xPG decides whether to execute request based on limits set by the CP)
* PFT: No essential performance, since the PFT does not communicate with or impact the xPG in any way
* CP: Cannot cause xPG to exceed pre-set clinician limits in any failure mode
* EPG: Stimulation output parameters cannot exceed maximum clinician set limits by 10%

Expected service life for the non-single use components of the system are as follows:

* CP: 1 year
* PoP: 1 year
* PPC: 1 year
* Leads: 5 years
* IPG: 10 years
* PFT: 1 year
* EPG: 1 year

## Least Favorable Conditions

* PoP: The PoP is intended to operate in normal house hold conditions. There are no harsh environments intended for this device. It operates via rechargeable batteries. Based on this intended use, least favorable conditions for the PoP are addressed via standard stresses identified by IEC 60601 such as ESD, drop test, etc. and with device running on battery without recharge attached.
* PPC: The PPC is intended to operate in normal house hold and clinical setting conditions. There are no harsh environments intended for this device. It operates via rechargeable batteries. Based on this intended use, least favorable conditions for the PPC are addressed via standard stresses identified by IEC 60601 such as ESD, drop test, etc. and with device running on battery without recharge attached and in IPG charge mode.
* PFT: The PFT is intended to operate in normal clinical setting. There are no harsh environments intended for this device. It operates on primary cell batteries in only one mode which is in communication with CP. Based on this intended use, least favorable conditions for the PFT are addressed via standard stresses identified by IEC 60601 such as ESD, drop test, etc. and with device communicating with CP.
* CP: The CP is intended to operate in normal clinical setting. There are no harsh environments intended for this device. It operates via rechargeable batteries. It must identify viable devices in range of communication and pair with only one available device. Based on this intended use, least favorable conditions for the CP are addressed via standard stresses identified by IEC 60601 such as ESD, drop test, etc., with device running on battery without recharge attached, in communication with another device such as an IPG, EPG, PFT, or PoP with other available devices in range.
* EPG: The EPG is intended to operate in normal house hold and clinical setting. There are no harsh environments intended for this device. It operates via primary cell batteries. It must communicate with a PoP or CP. Based on this intended use, least favorable conditions for the EPG are addressed via standard stresses identified by IEC 60601 such as ESD, drop test, etc. and in communication with a PoP or CP in range.

# Assumptions

## System Assumptions

1. Rechargeable implanted system has a seven-year battery life.

## First pass effectiveness estimations

1. The use of labeling as mitigation is estimated at 50% for first-pass risk analysis.
2. Embedded design mitigations are estimated at 99% for first-pass risk analysis.
3. Design FMEA mitigations are estimated at 95% for first-pass risk analysis.
4. Process FMEA mitigations are estimated at 95% for first-pass risk analysis.
5. Bench testing mitigations is estimated at 90% for first-pass risk analysis.

Probabilities are further refined upon review of the assessment with input from the development team and clinician input.

# Device or System-Related Risk

Level and acceptability of the SCS system related risk is outlined in the following table. Level of risk at each released revision of this analysis is shown in one column. Final risk represents level of risk after evaluation for level of risk and consideration and implementation of additional controls or mitigations and/or a re-evaluation of the risk scenario. The final risk assessment may also be updated post market release based on field surveillance data.

Initial Risk: First risk analysis of the system. The initial cumulated risk analysis prior to implementation of additional controls.

Final Risk: Risk assessment after review of effectiveness of initial risk assessment and after implementation of additional controls and further analysis. Final risk assessment is updated from post market surveillance data.

Table 3 - Device or System-Related Risk

| **Hazard** | Severity Rating | Rev 1.1 Risk | Rev 1.2 Risk | Rev 1.3 Risk | Rev 1.4 Risk | Rev 1.5 Risk | Rev 1.6 Risk | Rev 1.7-1.9 Risk[[1]](#footnote-1) | Rev 1.10-1.11 Risk | Rev 1.10 Occurrence Rating | Rev 1.10 Occurrence Rate |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Under Stimulation Non-Surgical |  | 10 | 10 | 10 | 10 | 10 | 10 | 10 |  |  |  |
| Under Stimulation Surgical Intervention Required |  | 16 | 16 | 16 | 16 | 16 | 12 | 12 |  |  |  |
| Allergen Exposure |  | 9 | 9 | 9 | 9 | 9 | 9 | 9 |  |  |  |
| Bio-incompatibility |  | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |  |  |
| Bio-instability |  | 9 | 9 | 9 | 9 | 9 | 9 | 9 |  |  |  |
| CSF Leak |  | 3 | 3 | 3 | 3 | 3 | 3 | 3 |  |  |  |
| Environmental Damage |  | 4 | 4 | 4 | 4 | 4 | 4 | 4 |  |  |  |
| Erosion |  | 15 | 15 | 15 | 3 | 3 | 3 | 3 |  |  |  |
| Excessive Heat – Moderate |  | 12 | 6 | 6 | 6 | 6 | 6 | 6 |  |  |  |
| Excessive Heat – Severe |  | 12 | 12 | 12 | 12 | 12 | 12 | 12 |  |  |  |
| Infection |  | 9 | 9 | 9 | 9 | 9 | 9 | 9 |  |  |  |
| Infection of Central Nervous System or Spinal Canal |  | 4 | 4 | 4 | 4 | 4 | 4 | 4 |  |  |  |
| Misleading Information |  | 3 | 6 | 3 | 3 | 6 | 6 | 6 |  |  |  |
| Neural Compression or Damage |  | 12 | 12 | 12 | 12 | 12 | 12 | 12 |  |  |  |
| Overstimulation Non-Surgical Correction & Non-Permanent |  | 2 | 2 | 2 | 2 | 2 | 2 | 2 |  |  |  |
| Overstimulation Surgical Correction required to repair system |  | 12 | 12 | 12 | 12 | 12 | 12 | 12 |  |  |  |
| Overstimulation - Permanent Damage | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |  |  |  |
| DC Offset or Leakage - Charge Imbalance or DC Leakage |  | 2 | 6 | 6 | 6 | 6 | 6 | 8 |  |  |  |
| Excess Charge Density or Current Density |  | 12 | 9 | 9 | 9 | 9 | 9 | 9 |  |  |  |
| Toxicity |  | 8 | 4 | 4 | 4 | 4 | 4 | 4 |  |  |  |
| Trauma |  | 9 | 9 | 9 | 9 | 9 | 9 | 9 |  |  |  |
| Electrical Shock |  | 10 | 6 | 6 | 6 | 6 | 6 | 6 |  |  |  |
| Unintended Effect |  | 12 | 6 | 6 | 6 | 3 | 3 | 3 |  |  |  |
| Unintended Revision Surgery | [3](http://intranet/sites/qig/Neuromodulation/Development/Risk%20Management/QARE%200139%20SCS%20for%20Pain%20Therapy%20Risk%20Assessment/QARE%200139%20SCS%20for%20Pain%20Therapy%20Risk%20Assessment.docx#_Hlk326131024) | 12 | 12 | 12 | 12 | 12 | 12 | 12 |  |  |  |

Table 4 - Risk Levels of Acceptability

|  |  |
| --- | --- |
|  | Over Threshold |
|  | ALARP / Justification |
|  | Broadly Acceptable |

NOTE: defines the color codes f levels of acceptability.

# Procedure-Related Risk

The following are procedural related risks of the SCS therapy. Risk related to the system or risk that is controlled by the system design and labeling is not included here. Risks outlined here are procedural related. These procedural risks are controlled directly by either the clinician or clinic and its procedures or they are unavoidable risks resulting from the procedure and are not reducible. For this reason, occurrence rates are not controllable or calculated. These risks are addressed in risk assessment by disclosure to patient and clinician.

* Edema & Seroma with a severity rating of 2
* Infection with a severity rating of 3
* Infection of Central Nervous System or Spinal Canal with a severity rating of 4
* Trauma with a severity rating of 3
* Unintended Revision Surgery with a severity rating of 3
* Nerve Compression or Damage leading to paralysis / weakness / numbness with a severity of 4
* Bio-incompatibility with a severity rating of 3

# Severity and Occurrence Calculation

Severity and Occurrence calculations are defined and documented in risk plan and are restated here for reference.

## Severity Criteria

The Severity Criteria for each Failure Effect is graded on a 1-5 scale according to the following criteria:

Table 5 - Risk Severity

|  |  |  |
| --- | --- | --- |
| **Rating** | **Severity** | **Criteria** |
| 5 | Catastrophic | Results in patient death |
| 4 | Serious | Serious injury or permanent impairment requiring hospitalization or invasive intervention |
| 3 | Moderate | The hazard could either directly result in moderate injury to the patient or operator, or indirectly affect the patient such that delayed or incorrect information could result in moderate injury to the patient requiring professional medical intervention. |
| 2 | Minor | Temporary injury or impairment not requiring professional medical intervention |
| 1 | Negligible | No Noticeable Effect on Product or Process, e.g. product blemish, inconvenience, or temporary discomfort |

The severity level for each hazard is determined for SCS for pain therapy using criteria outlined in the preceding table. The severity for each hazard is documented in EEEX 0071 SCS Hazard Summary and is shown in Table 3 - Device or System-Related Risk. EEEX 0071 Hazard Summary is a separate document from this risk assessment in order to provide consistency in the organization from one aspect of the SCS project to another, and to assure the levels of severity are appropriate for the therapy.

## Occurrence Criteria

The frequency (probability of occurrence, F) is graded on a 1-5 scale per guidance in the following table:

Table 6 - Risk Probability

|  |  |  |
| --- | --- | --- |
| **Frequency of Failure Cause (F)** | **Rate (Device Months)** | **Rating** |
| **Frequent** | x ≥ 0.010000 | 5 |
| **Probable** | 0.010000 > x ≥ 0.001000 | 4 |
| **Occasional** | 0.001000 > x ≥ 0.000100 | 3 |
| **Remote** | 0.000100 > x ≥ 0.000010 | 2 |
| **Improbable** | 0.000010 > x | 1 |

## Risk Criteria

Table 7 - Risk Evaluation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Risk Severity Assessment** | | | | |
| **Probability of Occurrence** | **Negligible**  **(1)** | **Minor**  **(2)** | **Moderate**  **(3)** | **Serious**  **(4)** | **Catastrophic (5)** |
| **Frequent (5)** |  |  |  |  |  |
| **Probable (4)** |  |  |  | **Over Threshold** | |
| **Occasional (3)** |  |  | **ALARP / Justification** | |  |
| **Remote (2)** | **Broadly Acceptable** | | |  |  |
| **Improbable (1)** |  |  |  |  |  |

## Occurrence Estimation Method

Probabilities were estimated initially and further refined upon review of the assessment with input from the development team and clinician input. A seven year product life was chosen as the most representative duration of patient exposure.

**E0 Estimation based on Judgment - Will Occur in first month - 1.0 device-month**

Will occur immediately if not controlled, high probability of exposure. All patients will see this with-in 1 month of implant life => 1.0 device-month.

**E1 Estimation based on Judgment - Will Occur in device lifetime - 0.011905 device-months**

Will occur if not controlled, high probability of exposure. All (100 in 100) patients will see this in a 7-year implant life. 100 patients, 7 years, equates to 8,400 device-months. 100 patients in 8,400 device-months => 0.011905 device-months.

**E2 Estimation based on Judgment - Very Likely - 0.008929 device-months**

Very likely occurrence, good probability of exposure. Three quarters (75 in 100) patients will see this in a 7-year implant life. 100 patients, 7 years, equates to 8,400 device-months. 75 patients in 8,400 device-months => 0.008929 device-months.

**E3 Estimation based on Judgment – Likely - 0.005952 device-months**

Likely occurrence, good probability of exposure. Half (50 in 100) patients will see this in a 7-year implant life. 100 patients, 7 years, equates to 8,400 device-months. 50 patients in 8,400 device-months => 0.005952 device-months.

**E4 Estimation based on Judgment – Moderate - 0.002976 device-months**

Moderately rare occurrence, low probability of exposure. 25 in 100 patients will see this in a 7-year implant life. 100 patients, 7 years, equates to 8,400 device-months. 25 patients in 8,400 device-months => 0.000238 device-months.

**E5 Estimation based on Judgment – Moderate - 0.000238 device-months**

Moderately rare occurrence, low probability of exposure. 2 in 100 patients will see this in a 7-year implant life. 100 patients, 7 years, equates to 8,400 device-months. 2 patients in 8,400 device-months => 0.000238 device-months.

**E6 Estimation based on Judgment – Unlikely - 0.000024 device-months**

Unlikely occurrence, low probability of exposure. 2 in 1,000 patients will see this in a 7-year implant life. 1,000 patients, 7 years, equates to 84,000 device-months. 2 patients in 84,000 device-months => 0.000024 device-months.

**E7 Estimation based on Judgment - Very Unlikely - 0. 000002 device-months**

Very unlikely occurrence, good probability of exposure. 2 in 10,000 patients will see this in a 7-year implant life. 10,000 patients, 7 years, equates to 840,000 device-months. 2 patients in 840,000 device-months => 0.000002 device-months.

# Final Risk-Based Design Input and Traceability

Final risk-based design input will be an outcome of a later revision of this analysis.

Traceability of hazard to mitigation related specifications and verifications will be based on the hazard ID assigned to each root scenario as previously described in EEPL 0042 IPG System Risk Management Plan. The specific method will initially be via a spreadsheet-based tracing matrix. Requirements management software may be implemented for this traceability later.

# Fault Tree Analysis Key

Key for System Component Identification in Fault Tree Analysis diagrams:

EVENT OR MITIGATION

OR GATE

P=1-(1-P1)\*(1-P2)\*(1-PN)

AND Gate

P=P1\*P2

TRANSFER

**Lead System**

**Tunneling tool**

**Lead**

**Test stim lead**

**Introducer**

**Implantable Pulse Generator (IPG)**

**Clinician Programmer**

**Patient Programmer-Charger**

**Pocket programmer**

**External Pulse Generator (EPG)**

**All Systems**

Indicates a referenced value

# Features and Functions Analyzed for Risk

## Implantable Pulse Generator IPG)

* Programmable Current Output
* Balanced current output, total current across channels sums to zero
* Rechargeable
* MICS antenna in header
* Two Header versions (3x8, 2x12)
* Latest parameters stored in RAM
* MICS communication
* Configured by CP but configuration and data resides on IPG, not CP

## External Pulse Generator (EPG)

* The power supply is a replaceable primary cell battery that can easily be changed by the user.
* Uses plug-in screener cables to attach to the implanted leads
* External, hand-held,
* Connects to programmer
* Reusable and non-sterile
* Uses an external, mechanical, on-off button to turn stimulation off. EPG off button works in similar way as IPG magnet. Holding button for 2 seconds turns stim off; holding for more than 5 seconds puts EPG in storage mode.
* Reports status of its internal battery capacity to programmers
* Uses a ground pad, ground pad cable, and ground pad cable connection for unipolar stimulation
* Presents to CP as a 2x12 or 3x8 IPG depending on which cable is connected.

## Clinician Programmer (CP) and Patient Feedback Tool (PFT) accessory

* Communicate with any IPG or EPG, stays in session with an IPG or EPG until connection is lost
* MICS communication only (1 meter range), communicates with a single IPG picked from all IPGs in range based on serial number pick list
* Battery power
* Display Interfaces
* Stim parameter programming
* Stored information
* IPG communication (format, information, etc.)
* IPG trouble shooting
* Error code decode
* Set stim ± settings from graphic stim area
* Pre-surgery prep
* Potential feature: Data aggregation
* Off command is sent by MICS to selected serial number only, configuration data retained
* Configures IPG but IPG retains configuration data, not CP
* Patient feedback tool used to communicate grip intensity to CP

## Patient Programmer-Charger (PPC)

Features and functions of the PPC are:

* Paired with a single, individual, IPG by CP
* Allows re-pairing in the field for new PPC or new PoP via password access.
* The power supply is a rechargeable battery that charges from mains power
* Can run on rechargeable battery or while charging from mains power
* Displays On-Off stimulation status
* Displays, selects, changes stimulation programs
* Displays, selects, changes stimulation pulse width
* Displays, selects, changes stimulation frequency
* Displays, increments, decrements stimulation amplitude
* Changes amplitude and pulse width of individual pulses
* Displays IPG battery status
* Displays its own battery status
* Notifies on IPG error codes
* Recharges IPG battery
* Individual pulse adjustments with-in CP programmed parameters
* Charger is rechargeable
* Operates while plugged in wall for charging or stand-alone on battery
* Separate charge coil
* MICS communication paired to 1 IPG, 1 meter range
* ‘Off’ is sent by MICS to paired IPG only, configuration data retained

## Pocket Programmer (PoP)

Features and functions of the PoP are:

* MICS paired communication only
* Paired with a single, individual, IPG by CP
* The power supply is a rechargeable battery
* Displays On-Off stimulation status
* Displays, selects, changes stimulation programs
* Displays, increments, decrements stimulation amplitude
* Displays IPG battery status
* Displays its own battery status
* Notifies on IPG error codes
* PoP ‘Off’ is sent by MICS to paired IPG only, configuration data retained
* Cannot adjust PW or frequency

## Patient Magnet

Features of the magnet are:

* Same function north or south polarity
* Applied for 5 contiguous seconds turns IPG off (storage mode, including stim off). IPG can only be turned back on by applying charging coil of PPC. The IPG cannot be turned back on by the CP or PoP. Hardware shut down so works even if processor is in nonfunctional state.
* Apply magnet swipe turns stim off but not IPG off. Can be turned back on by PoP, PPC, or CP, or applying magnet for 2 seconds. Configuration data retained
* ‘Storage Mode’ is 5-second magnet, default values retained

## System-wide

* Putting IPG into storage mode function saves only default parameters
  1. CP MICS communication for putting IPG in storage mode
  2. PPC MICS communication only way to bring IPG back from storage mode
  3. PoP no Full function
  4. Magnet communication only 5-second or longer initiates storage mode
* Low battery alarm sequence
  1. IPG low battery warning to all external devices
  2. Battery critical warning to all external devices
  3. IPG stim output stopped (too low to stim) warning to all external devices
  4. IPG MICS communication stopped (storage mode until recharge)
  5. IPG hardware cut-out no communication

## 12 & 8 Polar Percutaneous Lead

* Stretchable lead body
* 12 or 8 conductors

## CP Diagnostics of IPG

* Lead impedance check
* Current state of IPG battery
* Number of recharges
* Duration each program has been running
* Estimated recharge interval

## Accessories

* Tunneling Tool
  + Provides path for implanting lead
* Anchor
  + Controls lead migration
* Elevator
  + Separates dura/epidural space for insertion of paddle lead.
* Introducer Needle

Needle w/ stylet inserted

Pick Location for cut based on dermas target

**Introducer needle process**

Puncture ligamentum flavum once through muscle, fascia, and between vertebra

Tilt needle to oblique angle (approximately 30°) with bevel of needle up prior to penetrating muscle and fascia and point to ligamentum flavum target

Perpendicular ‘push’ through dermas (may do scalpel cut first)

Continue penetration to epidural space but not through dura (approx 2/3 distance)

Optional check / confirm position with lateral fluoroscopy

Optional check / confirm position with lateral fluoroscopy

Location verification

- or -

Alternate: cut / insert lead blank / check

Normal: cut / pop / check with air

Optional check for loss of resistance using needle and syringe plunger

Confirm lead in place with fluoroscopy

Pass lead to target

Optional: Use needle ‘shovel’ to assist in lead guidance

test stim

Remove needle

Trial Stim

Shovel

Shoulder

Proximal End of Needle

# Device or System-Related Risk

## Under Stimulation Non-Surgical - Part 1

Implant pocket too deep

Occurrence =

0.000024 (E6)

**Ref# 031, 058**

Not enough time spent on recharge

Occurrence =

0.008929 (E2)

**Ref# 132**

PPC failure

Occurrence =

0.005952 (E3)

**Ref# 221**

PPC IFU for IPG battery charge Instructions, 50% effective

Occurrence = 0.004465 (M6)

IPG IFU Labeling on implant depth, 50% effective

Occurrence= 0.000012 (M5)

PPC DFMEA, 99% effective

Occurrence = 0.000060 (M492)

**Under Stimulation Non-Surgical**

Occurrence =  5 0.025354

Severity =  2

Risk Index =  10

Implanted Neurostimulator System

External Pulse Generator System (EPG)

Rechargeable IPG Battery discharge

(100% of market)

Insufficient recharge signal

Excessive time between recharge

Occurrence = 0.000238 (E5)

**Ref# 089**

Design requirement for IPG battery status to flash when low on PPC & PoP, 50% effective

Occurrence = 0.000119

(M10)

Patient cannot locate IPG to recharge

Occurrence = 0.008929 (E2)

**Ref# 090,114**

PPC coil locating display, 50% effective

Occurrence = 0.004465 (M3)

Instructions in patient PPC manual on locating IPG, 50% effective

Occurrence = 0.004465 (M4)

Occurrence = 0.000020

Occurrence = 0.025354

Occurrence = 0.004597

Occurrence = 0.004597

Occurrence = 0.00012

Occurrence = 0.025342

PPC Labeling guidance for Recharge frequency instructions, 50% effective

Occurrence = 0.000119

(M8)

Design requirement for IPG Battery capacity indicator on CP, PPC, PoP, 50% effective

Occurrence = 0.000119

(M9)

From Part 2

From Part 7

PPC battery dead – can’t charge IPG

Occurrence = 1.0 (E0)

**REF # 334**

Design requirement to allow charging PPC while charging IPG 99% effective

Occurrence = 0.010000 (M1)

Design requirement for PPC battery status indicator to flash when low, 99% effective

Occurrence = 0.010000

(M2)

Occurrence = 0.000100

From Part 9

Stim parameters set too low

Use a 2nd PPC, 50% effective

Occurrence = 0.002976

(M373)

Occurrence = 0.000000

Occurrence = 0.000000

PPC SW Validation 99% effective

Occurrence = 0.000060 (M7)

## Under Stimulation Non-Surgical - Part 2

Exposure to strong EMI fields such as:

(Dental drills, ultrasonic probes, bone growth stimulation, laser procedures, household items)

Occurrence = 0.000024 (E6)

**REF # 335**

Labeling guidance to:

* avoid or limit exposure EMI intensive procedures
* disclose potential effects of exposure EMI

50% effective, Occurrence =0.000012 (M13)

EMI from Electrocautery

Occurrence = 0.005952 (E3)

**Ref# 057,123**

Labeling in warnings to use caution with these devices and notify clinician that a stimulator is implanted.

50% effective

Occurrence = 0.008875

(M17)

IFU physician and patient manual labeling to avoid MRI

Occurrence = 0.500000 (M11)

Successful EMI / EMC testing of PG’s, 90% effective

Occurrence = 0.049301

(M23)

EMI from MRI causes IPG re-set

Occurrence = 1.00 (E0)

**Ref# 159**

Design requirement, device faults that could be caused by EMI such as:

   MICS communication error

   Watch dog timeout

   Corrupted memory

   etc.

Have specific fault detection and recovery implemented in the firmware and / or hardware.

These include:

    Returning error codes to user

    Locking out corrupted programs

    Turning off Stim

    Setting IPG to idle mode

    Returning IPG to default settings

    Etc.

Depending on permanency or severity, some are automated, some are resettable by PoP or PPC, while others require CP communication to address

99% effective, Occurrence = 0.004930 (M24)

No xPG output due to device off-mode reset, etc. that is recoverable by PoP, PPC, or CP

Occurrence = 0.000001

Occurrence = 0.493006

Occurrence = 0.020566

IPG Design requirement for CRC check on all commands before implementing, 99% effective

Occurrence = 0.000089

(M20)

Data corruption in wireless CP command resulting in erroneous low current setting

Occurrence = 0.008929 (E2)

**Ref# 224**

Design requirement for PoP & PPC limited by preset stim values set by Clinician using CP and are stored in IPG for read by PoP & PPC, 99% effective, Occurrence = 0.010000 (M21)

Patient programs their IPG to low current

Occurrence =1.00 (E0) **Ref# 222**

Design requirement for current increase in CP, 99% effective, Occurrence = 0.010000 (M19)

Clinician programs IPG to low current

Occurrence =1.00 (E0)

**Ref# 223**

Wrong patient is programmed to lower current because they are in range of intended patient

Occurrence = 0.008929 (E2)

**Ref# 067**

Occurrence = 1.000000

xPG Design Requirement for filtered feedthroughs for EMI, 99% effective

Occurrence = 0.004930

(M12)

From Part 4

Occurrence = 0.000590

From Part 3

Occurrence = 0.005146

To Part 1

MICS Design requirement for CP to link by serial number with an IPG and only communicate to it, 100% effective

Occurrence = 0.000000 (M14)

Occurrence = 0.020565

Low IPG output recoverable by PoP, PPC, or CP

**Ref# 230**

EMI from high output ultrasonic, & radiation therapy

Occurrence = 0.005952 (E3)

**Ref# 057,123**

Exposure to medical treatments that passes current to the body from an external source

Occurrence = 0.005952 (E3)

**Ref# 057,123**

Occurrence = 0.017750

## Under Stimulation Non-Surgical - Part 3

Therapeutic magnets

Occurrence = 0.000024 (E6)

**Ref# 229**

Labeling for IPG to avoid therapeutic magnets, 50% effective

Occurrence = 0.000012

(M27)

Transcutaneous electrical nerve stimulation (TENS)

Occurrence = 0.000024 (E6)

**Ref# 228**

Labeling for precautions & guidelines to avoid exposure to TENS devices, 50% effective

Occurrence = 0.000012

(M28)

EMI-induced loss of stim, e.g. from Electronic Article Surveillance (EAS) gate or Theft Detector

Occurrence = 1.00 (E0)

**Ref# 227**

Labeling in precautions to avoid EAS gate edges, to walk through, and not to stand in or near,

Occurrence = 0.500000 (M318)

Labeling in IPG precautions to avoid RF or Microwave ablation, 50% effective

Occurrence = 0.000012

(M36)

RF, Microwave ablation

Occurrence = 0.000024 (E6)

**REF #230**

Lithotripsy interferes with or damages the IPG/External Pulse Generator (EPG)

Occurrence = = 0.000024 (E6)

**Ref# 231**

Labeling warning to not to use Diathermy, 50% effective

Occurrence = 0.000012

(M35)

Diathermy

Occurrence = 0.000024 (E6)

**Ref# 116,120**

Design Requirement for filtered feedthroughs for EMI, 99% effective Occurrence = 0.010000 (M12)

Occurrence = 0.005000

Labeling in IPG precautions & guidelines to avoid exposure to Lithotripsy, 50% effective

Occurrence = 0.000012 (M484)

PG Memory bit flipping or corruption, probability of occurrence = 0.000120 (A1)

Ionizing or non-ionizing radiation environment

Occurrence = 1.00 (E0)

**Ref# 122**

Design requirement to CRC only memory locations that are used (multi-writes, reduce opportunity for failure), 99% effective

Occurrence = 0.000001

(M29)

Occurrence = 0.005146

Occurrence = 0.000001

To Part 2

IPG is discharged between implant and post wound healing recharge.

Occurrence = 0.008929 (E2)

**Ref# 235**

Production requirement to assure 20% charge after final test, 95% effective

Occurrence = 0.000893 (M33)

Labeling guidance to read and confirm charge level and charge IPG in box as a precaution, 50% effective

Occurrence = 0.008929

(M34)

Design / process requirement for use by date on package labeling (done at manufacturing site at time of packaging), 99% effective

Occurrence = 0.000179

(M32)

Occurrence = 0.000000

IPG is discharged at time of implant

Occurrence = 0.008929 (E2)

**Ref# 234**

Occurrence = 0.017858

From Part 5

Occurrence =

## Under Stimulation Non-Surgical - Part 4

Lead migration up or down spinal cord column due to fall or other patient movement (i.e. new placement too far away for effective stim at present settings but correctable with new settings)

Occurrence = 1.00 (E0)

**Ref# 161**

Clinician Manual guidance on lead implant techniques, coiling, strain relief, use of anchor, no meandering, etc.

Occurrence = 0.500000 (M46)

Successful EMI / EMC testing, 90% effective

Occurrence = 0.000893

(M23)

Lead Anchor, 99% effective

Occurrence = 0.010000 (M47)

EMI-induced communication error

Occurrence = 1.00 (E0)

**Ref# 232, 097, 098, 099**

Device Compatibility

Verification Testing, 90%effective

Occurrence =

0.000893

(M39)

Re-program to different electrode pair, 90% effective

Occurrence = 0.100000

(M45)

PoP, PPC MICS paired communication design requirement, CP MICS communication by selecting from list of available serial numbers, 99% effective

Occurrence = 0.000089 (M40)

Occurrence = 0.000000

Occurrence = 0.000500

Occurrence = 0.000590

Design requirement for IPG functional reset to zero output if parity failure based on criteria, IPG behavior is to stop stimulating and attempt to correct, if true hard error it shuts down and disables that program, 99% effective, Occurrence = 0.000089 (M38)

Design requirement for parity check in stim ASIC each time register us used, 99% effective, Occurrence = 0.000089 (M37)

Data Corruption resulting in low current output

Occurrence = 0.008929 (E2)

**Ref# 076**

IPG in need of stim current increase by CP, PoP, or PPC

Occurrence = 0.008929 (E2)

**Ref# 233**

Occurrence = 0.008929

To Part 2

Patient can increase IPG output in predefined range, 90% effective

Occurrence = 0.000917

(M44)

Patient returns IPG to clinician settings when not intending to do so.

Occurrence = 0.008929 (E2)

**Ref# 236**

Multiple programs capability, 90% effective

Occurrence = 0.000917

(M42)

Clinician can reprogram limits and settings, 90% effective

Occurrence = 0.000917

(M43)

Occurrence = 0.000000

Due to disease progression, clinician settings are no longer effective

Occurrence = 0.000238 (E5)

**Ref# 237**

Occurrence = 0.009167

Design requirement to check calibration at stim on (source & sink), 99% effective

Occurrence = 0.000089 (M48)

Single fault: IPG Reference current high, Occurrence = 0.008929 (E2) **Ref# 238**

From Part 6

Occurrence = 0.000001

Occurrence = 0.000000

## Under Stimulation Non-Surgical - Part 5

Patient instructions on assembly of system, 50% effective

Occurrence = 0.004465

(M58)

PPC batteries placed wrong.

Occurrence = 0.008929 (E2)

**Ref# 239**

Patient not able to recharge IPG

Labeling guidance on patient selection criteria, 50% effective

Occurrence = 0.004465

(M100)

Occurrence = 0.000020

Patient cannot assemble PPC system

Occurrence = 0.008929 (E2)

**Ref# 240**

Replace with new EPG, PPC, CP, or PoP, 95% effective

Occurrence = 0.000089 (M53)

PPC DFMEA, 95% effective

Occurrence = 0.000446

(M492)

CP DFMEA, 95% effective

Occurrence = 0.000446

(M493)

PoP DFMEA, 95% effective

Occurrence = 0.000446

(M491)

Occurrence = 0.001786

Occurrence = 0.008929

To Part 3

Malicious denial of service

Occurrence = 0.000002 (E7)

**Ref# 018**

Proprietary device communication protocol between CP, PPC, PoP, and IPG, 99% effective

Occurrence = 0.000000

(M54)

Electro-mechanical conductor open failure

Occurrence = 0.008929 (E2)

**Ref# 109, 210**

Electrode pair in use (2 of 8)

Occurrence = 0.000048

(M49)

No stimulation output on electrode pair in use

Lead DFMEA, 95% effective

Occurrence = 0.000446

(M50)

Occurrence = 0.000000

Non-hazard: Alternate electrode pair available for use, Occurrence = 0.100000 (M55)

Hazard: Alternate electrode pair not available for use, Occurrence = 0.900000 (M56)

This is an estimate and is dependent on patient physiology as well as lead placement and programmer skill.

Occurrence 0.000000

Open Circuits

Occurrence = 0.000109

Note: Statistic involves pairs with-in a set of 8 and is more complicated than can be depicted in a fault tree. Calculation is as follows:

Using 2 random conductors out of a set of 8, chance one or both are failed if the chance of a single conductor failure is 0.000024, statistic is:

­nPk

where

n = number of opportunities = 2

k = number of occurrences = 1 and 2

p = probability of an occurrence = 0.000024(E6)

q = 1 - p

Probability of no failures = 2P0 = 0.999952

Probability of 1 of the 2 conductors failing = 2P1 = 0.000048

Probability of both conductors failing = 2P2 = 0.000000

Probability of 1 or 2 failures = 2P1 + 2P2 or 1 - 2P0 = 0.000048

PPC Battery rechargeable and not replaceable 100% effective Occurrence = 0

(M51)

EPG DFMEA, 95% effective

Occurrence = 0.000446

(M494)

PPC electro-mechanical failure

Occurrence = 0.008929 (E2)

**Ref# 035**

CP electro-mechanical failure

Occurrence = 0.008929 (E2)

**Ref# 153**

PoP electro-mechanical failure

Occurrence = 0.008929 (E2)

**Ref# 151**

EPG electro-mechanical failure

Occurrence = 0.008929 (E2)

**Ref# 151**

## Under Stimulation Non-Surgical - Part 6

To part 4

Patient loses PoP

Occurrence = 0.011905 (E1)

**Ref# 242**

Patient loses PPC

Occurrence = 0.011905 (E1)

**Ref# 242**

Device transitions to lower than needed stimulation output

Occurrence = 0.005952 (E3)

**Ref# 243**

Occurrence = 0.000142

Occurrence = 0.000001

Low or no stim

Occurrence = 0.000001

Design requirement magnet mode feature can be turned off or disabled by CP, 99% effective, Occurrence = 0.000119

(M59)

Magnet feature inadvertently switches stim off by environmental magnetic field.

Occurrence = 0. 011905 (E1)

**Ref# 241**

‘Stim on’ using PoP, 99% effective, Occurrence = 0.000119

(M62)

‘Stim on’ using PPC, 99% effective, Occurrence = 0.000119

(M60)

Occurrence = 0.000001

IPG design requirement for min 10 Gauss (1 Tesla) field to activate, 99% effective, Occurrence = 0.000119

(M398)

Design requirement for:

‘Full Stim Off’ or 5-second magnet ‘Off’: Only PPC can turn IPG stim back on (power ASIC), Note: 5s off is logic function, not processor so works if Processor is corrupt

PPC needs to get to charge screen with unpaired MICS communication

Magnet swipe stim ‘Off’: PPC, CP, PoP, and same magnet can turn stim back on

50% effective, Occurrence = 0.005953 (M85)

Occurrence = 0.000000

## Under Stimulation Non-Surgical - Part 7 (EPG)

ESD induced failure

Occurrence = 1.00 (E0), **Ref# 220**

EPG ESD requirements, 99.99% effective

Occurrence = 0.000100

(M69)

No output

Lead damaged from handling, does not fit EPG connection

Occurrence = 0.000024 (E6)

**Ref# 158**

Labeling includes symbol to not use if package damaged

Occurrence = 0.000012

(M64)

Compromised interconnects between components

Incompatible components, Occurrence = 0.000238 (E5) **Ref# 219**

Lead design requirement for roundness, min-max OD, insertion / withdrawal force, and contact spacing, IPG header design requirement for min-max ID, insertion / withdrawal force, and contact spacing, 99% effective, Occurrence = 0.000002 (M65)

EPG Cable DFMEA, 95% effective, Occurrence = 0.000298 (Mxxxx)

Electro-mechanical failure of Temporary screener cable conductor or insulator

Occurrence = 0.005952 (E3), **Ref# 160**

Occurrence = 0.000001

Use of spare, 50% effective, Occurrence =

0.002976, (M70)

Occurrence = 0.000127

Occurrence = 0.000003

Labeling guidance for single use

Occurrence = 0.000012

(M63)

Occurrence = 0.000000

To Part 1

EPG design requirement for lead impedance check (same as IPG), 99% effective

Occurrence = 0.000001, (M71)

EPG set to unipolar mode

Occurrence = 0.000238 (E5)

**Ref #388**

Occurrence = 0.000000

Poor ground connection

Very low usage, Probability=1%,

Occurrence=0.000060

Ground pad not sufficiently adhered to skin, Occurrence = 0.005952 (E3)

**REF # 337**

Ground pad cable becomes unplugged

Occurrence = 0.005952 (E3)

**REF # 338**

Occurrence = 0.005987

Occurrence = 0.000115

Battery capacity indicator displays ‘good’ but is not

Occurrence = 0.000238 (E5), **REF # 340**

Accidental press of ‘Off’ button on EPG

Occurrence = 0.011905 (E1)

**REF # 339**

EPG Design requirement for ergonomic design of ‘Off button’ to avoid unintentional press, 95% effective

Occurrence = 0.000595 (M67)

Design requirement for ‘stim on’ from PoP, CP, or PPC after EPG ‘off’ button press, 99% effective

Occurrence = 0.000119

(M68)

Occurrence = 0.000000

EPG DFMEA, 95% effective

Occurrence = 0.000012

(M494)

Electro-mechanical failure of EPG (high occurrence due to re-usability may use until fail)

Occurrence = 0.008929 (E2), **REF # 341**

EPG DFMEA, 95% effective

Occurrence = 0.000446, (M494)

From Part 8

Occurrence = 0.000009

Request new EPG from rep, 50% effective, Occurrence = 0.000446

(M401)

Occurrence = 0.000000

Design requirement for built-in EPG self-test with screener cable attached, 99% effective, Occurrence = 0.000089, (M393)

Ground pad dries up

Occurrence = 0.005952 (E3)

**REF # 385**

Occurrence = 0.011904

Multi-use wear-out, Occurrence = 0.002976 (E4)

**Ref# 391**

Water ingress, Occurrence = 0.005952 (E3)

**Ref# 389**

Early, random, & latent EPG wear-out, Occurrence = 0.002976 (E4), **Ref# 390**

Occurrence = 0.008929

Labeling guidance not to wear PoP / EPG in shower, etc., 50% effective, Occurrence = 0.002976, (M397)

## Under Stimulation Non-Surgical - Part 8 (EPG)

Change in output Occurrence = 0.000009

To Part 7

Occurrence = 0.000000

Operating temperature change, changes output, Occurrence = 0.008929 (E2)

**REF # 342**

Design requirement for EPG to operate with-in specification over range in office environmental temperatures, 99% effective

Occurrence = 0.000089, (M73)

EPG DFMEA 95% effective

Occurrence = 0.000446, (M494)

Patient feedback, 50% effective

Occurrence = 0.008929

(M402)

Design requirement for lead system impedance check, 99% effective

Occurrence = 0.000179

(M394)

Cable / EPG disconnect

Occurrence = 0.008929 (E2)

**REF # 383**

Weak EPG battery dies during use

Occurrence = 0.005952 (E3)

**REF # 343**

EPG Labeling guidance to always start with new battery, 50% effective

Occurrence = 0.008928

(M76)

Battery charge status indicator on EPG, 99% effective

Occurrence = 0.000179

(M77)

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.017856

Remove battery during use

Occurrence = 0.005952 (E3)

**REF # 372**

Dead EPG battery in use

Occurrence = 0.005952 (E3)

**REF # 343**

As in IPG, stim parameters are stored in NV RAM so return of power returns device to original settings but stim amplitude is set to 0, 99% effective

Occurrence = 0.000179

(M376)

Occurrence = 0.000002

Drop EPG causing lead-cable or cable-EPG disconnect, Occurrence = 0.008929 (E2)

**REF # 373**

Labeling guidance to tape & coil lead, 50% effective, Occurrence = 0.004465, (M377)

Design requirement for 10N connector retention force (cable - EPG), set-screw (cable-lead), 95% effective, Occurrence = 0.000446, (M378)

EPG Labeling guidance on proper battery installation, 50% effective, Occurrence = 0.000119, (M75)

EPG Design requirement for reverse polarity protection, 99% effective, Occurrence = 0.000002, (M74)

Batteries installed reverse

Occurrence = 0.000238 (E5)

**REF # 107**

Occurrence = 0.000000

Cable / lead disconnect

Occurrence = 0.008929 (E2)

**REF # 384**

Occurrence = 0.017856

Design requirement for EPG cable connect check, 99% effective

Occurrence = 0.000179

(M395)

Use EPG in harsh temperature - no output (<32, >120 F)

Occurrence = 0.000002 (E7)

**REF # 386**

No mitigation

Occurrence = 0.000002

(M0)

Program left on EPG from previous patient use, Occurrence = 0.008929 (E2)

**Ref# 419**

Previous EPG (with paired PoP) settings and programs are higher than required

Probability = 50%

Occurrence = 0.004465

Occurrence = 0.000005

CP software design requirement to provide Pop-up reminder to clear all EPG data prior to use on a new patient, 50%effective.

Occurrence = 0.002233

(M407)

Labeling Requirement for Instructions in User’s Manual to clear all EPG data prior to use on new patient, 50%effective.

Occurrence = 0.002233

(M406)

## Under Stimulation Non-Surgical - Part 9 (Implanted System)

Design requirement to disable functionality of CP, PPC, and PoP at safe low battery limit, 99% effective

Occurrence = 0.000119

(M79)

Over decreasing stimulation parameters, can’t return to higher stim due to low battery in CP, PPC, or PoP,

Occurrence = 0.011905 (E1)

**REF # 345**

Occurrence = 0.000036

Ambulatory under stim scenario presents due to physiological reasons

Occurrence = 0.005952 (E3)

**REF # 347**

To part 1

Under-shoot stim setting by double key press, key bounce, etc.

Occurrence = 0.011905 (E1)

**REF # 344**

Design requirement for Increase stimulation button on PPC, CP, PoP, 99% effective

Occurrence = 0.000119

(M78)

Design requirement for Increase stimulation button CP, PPC, PoP, 99% effective

Occurrence = 0.000060

(M78)

Occurrence = 0.000179

CP, PPC, and PoP design requirement to always display its own battery status, 99% effective

Occurrence = 0.000119

(M80)

Low battery on PoP or PPC prevents turn up

Occurrence = 0.005952 (E3)

**REF # 348**

If PoP low, PPC available or vice versa, 99% effective

Occurrence = 0.000000

(M84)

Design requirement for CP, PPC, and PoP to display its own battery status, 99% effective

Occurrence = 0.000000

(M80)

Design requirement for IPG, EPG to turn off at 2.75 volts, however, logic still functional down to 1.8 volts. , ie, device turns off before logic functionality corrupted, 100% effective

Occurrence = 0.000000

(M81)

IPG magnet sensor logic commands IPG off due to low IPG supply voltage

Occurrence = 1.0 (E0)

**REF # 346**

Occurrence = 0.000000

External / Environmental magnetic field turns IPG off

Occurrence = 0.005952 (E3)

**REF # 241**

Design requirement for 5-second dwell time before activating full stim off, 99% effective

Occurrence = 0.000060

(M82)

Design requirement for:

‘Full Stim Off’ or 5-second magnet ‘Off’: Only PPC can turn IPG stim back on (power ASIC)

PPC needs to get to charge screen with unpaired MICS communication

2-second magnet ‘Off’: PPC, CP, PoP can turn IPG back on

99% effective

Occurrence = 0.000000 (M85)

Design requirement for 2-second dwell time to activate temporary stim off, 99% effective

Occurrence = 0.000060

(M83)

Occurrence = 0.000000

Occurrence = 0.000000

## Under Stimulation Surgical Intervention Required - Part 1

**Under Stimulation Surgical Intervention Required**

Occurrence =  3 0.001328

Severity =  4

Risk Index =  12

Labeling explains proper tunneling procedure, 50% effective

Occurrence = 0.000012 (M86)

IPG broken wire bond

Occurrence = 0.000238 (E5), **Ref# 248**

IPG DFMEA, 95% effective, Occurrence = 0.000006 (M439)

Electro-mechanical lead failure mode

Electro-mechanical IPG wear-out failure mode

Electro-mechanical lead wear out failure mode

Electro-mechanical IPG failure mode

Rechargeable Cell Premature Battery Failure

(100% of market)

Occurrence = 0.000024 (E6)

**Ref# 086, 091, 092, 131, 152**

Instructions to implant in low-impact implant site location, 90% effective

Occurrence = 0.000024

(M88)

Other user induced electromechanical stress conditions

Occurrence = 0.000024 (E6)

**Ref# 103**

Twiddler syndrome

Occurrence = 0.000024 (E6) **Ref# 165, 261**

Fracture / short wear out lead conductor failure modes

Occurrence = 0.000238 (E5)

**Ref# 102, 179**

Functional IPG failure

Occurrence = 0.000024 (E6)

**Ref## 037, 038, 066**

**084, 085, 100, 101, 102, 103, 104, 135, 145, 247**

Out-of-box IPG failure

Occurrence = 0.000002 (E7)

**Ref# 245**

Instructions on guidance to test system before closing wound, 50% effective

Occurrence = 0.00000

(M89)

Out-of-box lead failure

Occurrence = 0.000002 (E7)

**Ref# 218**

Instructions on guidance to system test before close, 50% effective

Occurrence = 0.000000

(M89)

Labeling guidance to patients not to manipulate IPG, 50% effective

Occurrence = 0.000012 (M87)

Occurrence = 0.001328

Occurrence = 0.000024

Occurrence = 0.000024

Occurrence = 0.000048

Occurrence = 0.000000

Out-of-box lead failure is implanted

Occurrence = 0.008929 (E2)

**Ref# 162**

From Part 2

[Occurrence = 0.000714](#_Hlk323900392" \s "4,26809,26831,0,,Occurrence = 0.000714)

From Part 3

Out-of-box IPG failure gets implanted

Occurrence = 0.008929 (E2)

**Ref# 246**

Occurrence = 0.000000

Occurrence = 0.000036

Lead DFMEA, 95% effective, Occurrence = 0.000013 (M50)

Occurrence = 0.000262

Occurrence = 0.000117

Occurrence = 0.000048

Instructions around charging including to allow IPG to warm above freezing 50% effective

Occurrence = 0.000012

(M444)

Lead, IPG, extension labeling includes symbol for number of electrodes, 50% effective

Occurrence = 0.002976 (M461)

Model numbers based on number of electrodes, 50% effective

Occurrence = 0.002976 (M460)

Occurrence = 0.000000

Pulling new extension through tunneling tool using old extension Occurrence=0.000024 (E6)

Insert 12-contact lead into 2408 & tighten setscrew on lead body

Occurrence = 0.002976

Insert 8-contact lead into 2412 & tighten setscrew on lead body

Occurrence = 0.002976

Occurrence = 0.000012

Premature lead failure due to high stress from technique

Occurrence = 0.005952

SW design requirement causes error message if 8x into 12 or vice versa, 50% effective

Occurrence = 0.002976 (M485)

## Under Stimulation Surgical Intervention Required - Part 2

Post implant weight gain brings IPG / Programmer coupling out of range, Occurrence = 0.000024 (E6)

**Ref# 041,044**

Labeling guidance on implant depth range, 50% effective

Occurrence = 0.000012

(M92)

Device transitions to under stimulation state for some unrelated reason (includes SW)

Occurrence = 0.000024 (E6)

**Ref# 250**

Device antenna or other communication hardware failure

Occurrence = 0.000024 (E6)

**Ref# 042**

IPG migrates outside communication range

Occurrence = 0.008929 (E2) **Ref# 043**

Patient does not have physical and/or mental capacity to perform recharge activity

Occurrence = 0.005952 (E3)

**Ref# 252**

Occurrence = 0.000020

Lost recharge capability

Labeling guidance on patient screening for ability to recharge IPG on a recurring basis, 50% effective, Occurrence = 0.002976 (M93)

IPG flips and becomes outside communication range, Occurrence = 0.008929 (E2) **Ref# 040**

IPG anchoring (suture holes), 99% effective, Occurrence = 0.000179 (M91)

Insufficient recharge coupling

IPG Implanted too deep

Occurrence = 0.008929 (E2)

**Ref# 254**

IPG IFU Labeling on implant depth, 50% effective

Occurrence = 0.004465

(M5)

Labeling guidance to test system before closing, 50% effective

Occurrence = 0.004465

(M89)

Lead anchor, 99% effective

Occurrence = 0.000089

(M47)

Lead migration too far away and cannot be compensated for by new stim settings due to fall or other movement.

Occurrence = 0.008929 (E2)

**Ref# 142, 166**

Labeling guidance on implant location and lead routing to minimize migration, 50% effective

Occurrence = 0.004465

(M95)

Occurrence = 0.000000

Lead movement in header

Design requirement for torque limit wrench, 95% effective, Occurrence = 0.000446 (M94)

Occurrence = 0.000714

Occurrence = 0.000199

Occurrence = 0.017858

Occurrence = 0.000208

Occurrence = 0.000036

Loss of inter-connect contact

from under-torqued setscrew

Occurrence = 0.008929 (E2)

**Ref# 253**

Lead conductor short

Occurrence = 0.000024 (E6)

**Ref# 251**

IPG design requirement for constant current source, no change in output, 99% effective

Occurrence = 0.000000

(M96)

To Part 1

Occurrence = 0.000009

Design requirement for PPC to indicate recharge quality to user including indicator of direction to move recharge head to attain maximum recharge quality, 50% effective, Occurrence = 0.002976 (M434)

Occurrence = 0.000060

## Under Stimulation Surgical Intervention Required - Part 3

Increasing electrode impedance to point of pulse clipping

Occurrence = 0.000238 (E5)

**Ref# 139**

Electro-mechanical lead failure that leads to open channel and other channels are not useable

Occurrence = 0.000238 (E5)

**Ref# 136, 137, 138, 140**

To Part 1

Therapy ineffective for physiological reasons

Occurrence = 0.008929 (E2)

**Ref# 256**

Non-compliant patients selected

Occurrence = 0.008929 (E2)

**Ref# 255**

Labeling guidance on patient selection criteria, 50% effective

Occurrence = 0.008929

(M100)

Trial stimulation phase, 90% effective

Occurrence = 0.001759

(M101)

Occurrence = 0.000016

Occurrence = 0.017585

Occurrence = 0.000595

Poor contact made at implant (set screw not torqued, lead not fully inserted, etc.)

Occurrence = 0.000238 (E5)

**Ref# 154, 253**

Labeling guidance on proper insertion and to perform system integration check prior to closing implant, 50% effective

Occurrence = 0.000119

(M97)

Occurrence = 0.000119

No Mitigation

Occurrence = 0.000479

(M0)

Occurrence = 0.000476

## Allergen Exposure

Design criteria for no latex in products, 100% effective

Occurrence = 0.000000

(M102)

Allergic to latex

Occurrence =

Occurrence = 0.08

**Ref# 167**

Manufactured in controlled environmental area, 99.99% effective

Occurrence = 0.000100

(M103)

Bioburden

Occurrence =

Occurrence = 1.00 (E0)

**Ref# 168**

IPG DFMEA, 95% effective

Occurrence = 0.000298

(M439)

Electromechanical failure exposes internal IPG components to body fluid

Occurrence = 0.005952 (E3)

**Ref# 257**

No mitigation at this time

Allergic reaction to biocompatible IPG/component materials:

Occurrence = 0.000002 (E7)

**Ref# 012, 013**

**Allergen Exposure**

Occurrence =  3 0.000102

Severity =  3

Risk Index =  9

Occurrence = 0.000102

IPG PFMEA maintain hermetic seal, 95% effective,

Occurrence = 0.000298

(M104)

Occurrence = 0.000000

Occurrence = 1.00

Body contact with system components

Implantable Leads Contact

Occurrence = 1.00 (E0) **Ref# 406**

IPG Contact

Occurrence = 1.00 (E0)

**Ref# 407**

CP Contact

Occurrence = 1.00 (E0)

**Ref# 408**

EPG Ground Pad Contact (1-2 weeks)

Occurrence = 1.00 (E0) **Ref# 409**

EPG Contact

Occurrence = 1.00 (E0)

**Ref# 405**

PPC Contact

Occurrence = 1.00 (E0)

**Ref# 404**

PoP Contact

Occurrence = 1.00 (E0) **Ref# 404**

Accessories Contact (Tunneling tool, Needle, Anchor, Bore plug, etc.)

Occurrence = 1.0 (E0) **Ref# 412**

## Bio-incompatibility

10993-1 testing, 99.99% effective

Occurrence = 0.000100

(M112)

10993-1 Leachables Tox, 99.99% effective

Occurrence = 0.000100

(M114)

Bio-incompatible Implantable Materials

Occurrence = 1.00 (E0)

**Ref# 170**

EtO Sterilization process, 99.99% effective

Occurrence = 0.000100

(M116)

10993-7 testing, 99.99% effective

Occurrence = 0.000100

(M112)

EtO residuals

Occurrence = 1.00 (E0)

**Ref# 171**

**Bioincompatibility**

Occurrence =  1 0.000000

Severity =  3

Risk Index =  3

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000000

Use of materials already used in implant environment, 99.999% effective

Occurrence = 0.000100

(M113)

10993-1 testing, 99.99% effective

Occurrence = 0.000100

(M112)

Labeling guidance for full IPG charge to allow wound healing before recharge is needed, 50% effective

Occurrence = 0.500000

(M115)

Bio-incompatible skin contact materials

Occurrence = 1.00 (E0)

**Ref# 170**

Occurrence = 0.000000

Use of materials already used in patient environment, 99.999% effective

Occurrence = 0.000100

(M113)

Leads Contact

Occurrence=

1. (E0)

**Ref# 410**

Accessories Contact (Tunneling tool, Needle, Anchor, bore plug, etc.) Occurrence = 1.0 (E0) **Ref# 412**

IPG Contact

Occurrence= 1.0 (E0) **Ref# 411**

PPC, PPC coil, or PPC strap surface contact

Occurrence =

1.0 (E0)

**Ref# 413**

Adhesive Pads surface contact

Occurrence =

1.0 (E0)

**Ref# 414**

Occurrence = 1.0

Occurrence = 1.0

PoP surface contact

Occurrence =

1. (E0)

**Ref# 415**

CP surface contact

Occurrence =

1. (E0)

**Ref# 416**

## Bio-instability

Labeling for a single use of IPG and Leads, 50% effective

Occurrence = 0.000119

(M120)

Customer re-sterilization

Occurrence = 0.000238 (E5)

**Ref# 258**

In-vivo preclinical testing, 90% effective

Occurrence = 0.100000 (M117)

In-vitro bench testing for biostability, 99.99% effective

Occurrence = 0.000100 (M119)

Bio-instable materials (environmental break down of materials in-vivo such as MIO, ESC)

Occurrence = 1.00 (E0)

**Ref# 172**

Occurrence = 0.000000

**Bioinstability**

Occurrence =  3 0.000119

Severity =  3

Risk Index =  9

Degraded material

Occurrence = 0.000119

Use of materials already used in implant environment, 99.999% effective

Occurrence = 0.000100 (M113)

## CSF Leak

Labeling guidance to start introducer needle one vertebra dorsally from ligamentum flavum target, effectiveness = 50%, Occurrence = 0.001488 (M429)

**CSF Leak**

Occurrence =  1 0.000004

Severity =  3

Risk Index =  3

Design requirement for multiple stylet shapes or stiffness, 99% effective

Occurrence = 0.000003

(M125)

Occurrence = 0.000000

Occurrence = 0.000002

Labeling guidance to confirm location in epidural space, effectiveness = 50%, Occurrence = 0.001488 (M431)

Puncture dura with introducer needle, Occurrence = 0.005952(E3)

Design requirement for ‘shoulder’ on needle to produce loss of resistance and tactile feedback when penetrating ligamentum flavum, effectiveness = 50%

Occurrence = 0.001488 (M432)

Occurrence = 0.000002

Design requirement to have ‘shovel’ feature on needle to reduce potential for dura puncture, effectiveness = 50%, Occurrence = 0.002976 (M424)

Puncture dura with lead

Occurrence = 0.002976(E4) **Ref# 174**

Design requirement for ‘shovel’ tip on needle to help guide lead in path parallel to dura, effectiveness = 90%, Occurrence = 0.000298 (M424)

Labeling guidance to tilt needle to oblique angle (approximately 30°) with bevel of needle up prior to penetrating muscle and fascia and point to ligamentum flavum target

50% effectiveness,

Occurrence = 0.002976 (M427)

Design requirement for 2 different needle sizes to accommodate various anatomies (approximate 4” provided in original packaging with approximate 6” needle available as accessory, effectiveness = 50%, Occurrence = 0.002976 (M426)

Labeling guidance to use care in epidural placement and not use excessive force after loss-of-resistance stage of needle introduction, effectiveness = 50%, Occurrence = 0.001488 (M433)

Labeling guidance to start introduce needle one vertebra dorsally from ligamentum flavum target, effectiveness = 50%, Occurrence = 0.002976 (M429)

Design requirement for lead tip to be rounded and lead body to be non-stiff, effectiveness = 90%, Occurrence = 0.000298 (M203)

Labeling guidance to tilt needle to oblique angle (approximately 30°) with bevel of needle up prior to penetrating muscle and fascia and point to ligamentum flavum target to help guide lead in path parallel to dura

50% effectiveness,

Occurrence = 0.002976 (M427)

Occurrence = 0.000000

Occurrence = 0.002976

Elevator design: all edges radiused, no sharp edges, 90% effective

Occurrence = 0.000002

(M454)

Cut tissue dura with edges of elevator

Occurrence = 0.000024 (E6)

**Ref# 194**

## Environmental Damage

Labeling in Clinician & patient manual that programmers use lithium batteries and to dispose per local regulation, 50% effective

Occurrence = 0.000024 (M131)

Disposal of CP, PoP, PPC battery

Occurrence = 0.000024 (E6)

**Ref# 088**

Device battery ruptures after explant due to sterilization

Occurrence = 0.000024 (E6)

**Ref# 125**

Labeling in Clinician manual regarding no re-sterilization, 50% effective

Occurrence = 0.000012

(M132)

Disposal Instructions in Patient Manual and Clinician Manual, 50% effective

Occurrence = 0.004465

(M126)

Transport of Contaminated, used medical device / packaging / accessories from implant, explant, & revision surgery

Occurrence = 0.008929 (E2)

**Ref# 176**

Guidance in Clinician manual to return all components of explanted system to manufacturer, 50% effective

Occurrence = 0.004465 (M129)

Disposal of explanted system and packaging

Occurrence = 0.008929 (E2)

**Ref# 259**

CP, PoP, PPC battery chemical leakage

Occurrence = 0.000024 (E6)

**Ref# 088**

**Environmental Damage**

Occurrence =  2 0.000040

Severity =  2

Risk Index =  4

Returned product mailer package designed (available but not packaged with device), 90% effective

Occurrence = 0.000893

(M127)

Occurrence = 0.000004

Returned product mailer package designed (available but not packaged with device), 90% effective

Occurrence = 0.000893 (M127)

Occurrence = 0.000040

Occurrence = 0.000000

Guidance in Clinician manual to dispose of unreturned components per local regulation, 50% effective

Occurrence = 0.004465 (M128)

Occurrence = 0.000048

## Erosion - Part 1

Clinician instructions on preferred implant technique, 50% effective

Occurrence = 0.004465

(M133)

Leads erode into dura or arachnoid

Occurrence =

0.008929 (E2)

**Ref# 178**

Design requirement for soft anchor, 99% effective

Occurrence = 0.000060

(M143)

Anchor site erosion of sub-fascia tissue

Occurrence = 0.005952 (E3)

**Ref# 260**

Smooth IPG surface, compliant with EN45502-1 design requirement (no surface features that cause erosion), sharp edges, 90% effective

Occurrence = 0.000893

(M138)

IPG erosion

Occurrence =

0.008929 (E5)

**Ref# 113**

Clinician instructions on implant depth and pocket size, 50% effective

Occurrence = 0.004464 (M5)

Lead erosion (much less likely than IPG erosion)

Occurrence = 0.000024 (E6) **Ref# 177**

**Erosion**

Occurrence =  2 0.000026

Severity =  3

Risk Index =  6

Clinician instructions on preferred anchoring technique, 50% effective

Occurrence = 0.002976

(M142)

Occurrence = 0.000000

Occurrence = 0.000004

Occurrence = 0.000026

Design requirement for soft lead body and round tip, 99% effective

Occurrence = 0.000089

(M134)

Occurrence = 0.000000

From Part 2

Smooth lead surface, compliant with EN45502-1 design requirement (no surface features that cause erosion), sharp edges, 99% effective

Occurrence = 0.000089 (M138)

Design requirement for anchor, 99% effective

Occurrence = 0.000089

(M91)

IPG movement or migration

Occurrence = 0.008929 (E2)

**Ref# 040,113**

Labeling precautions to implant IPG, 50% effective

* Away from other IPG
* Away from bony structures
* Away from areas of restriction or pressure

Occurrence = 0.004465

(M140)

Design requirement for IPG suture holes, 90% effective

Occurrence = 0.000893

(M91)

Occurrence = 0.000000

Clinician and patient manual recommendation about patient activities, 50% effective

Occurrence =

0.0044665

(M141)

Occurrence = 0.000000

Smooth lead surface, compliant with EN45502-1 design requirement (no surface features that cause erosion), sharp edges, 90% effective

Occurrence = 0.000002

(M138)

Clinician instructions on implant depth and pocket size, 50% effective

Occurrence = 0.000012 (M5)

## Erosion - Part 2

Clinician and patient manual recommendation to patient not to manipulate IPG, 50% effective

Occurrence = 0.004464

(M144)

Labeling instructs Clinician to anchor IPG, 50% effective

Occurrence = 0.004464

(M145)

Twiddler Syndrome

Occurrence = 0.008929 (E6)

**Ref# 261**

Occurrence = 0.000020

Occurrence = 0.000022

To Part 1

Labeling guidance to recharge device prior to surgery to allow maximum healing time between initial surgery and first recharge event, 50% effective

Occurrence = 0.001488

(M139)

Additional pressure, irritation, at implant site with-in a few days of surgery

Occurrence = 0.002976 (E4)

**Ref# 332**

Labeling guidance to recharge over bandage, cloth material, or other means other than bare skin if heat sensation is felt, 50% effective, Occurrence = 0.001488 (M162)

Occurrence = 0.000002

## Excessive Heat - Part 1

IPG heat built-up during recharge 'edge effect' or otherwise

Occurrence = 1.0 (E0)

**Ref# 061, 064, 129, 096**

Lead electromechanical failure of insulation

Occurrence = 0.008929 (E2)

**Ref# 188**

High-density leakage current at exposed lead conductor wire break

**Excessive Heat**

Occurrence =  2 0.000198

Severity =  3

Risk Index =  6

PPC design requirement to throttle recharge power (closed loop), 99% effective

Occurrence = 0.010000

(M150)

Occurrence = 0.000100

Occurrence = 0.000198

Occurrence = 0.000080

Lead electromechanical failure of conductor wire

Occurrence = 0.008929 (E2)

**Ref# 188**

Lead DFMEA 95% effective

Occurrence = 0.000004

(M52)

From Part 2

Heated IPG

PPC

Lead System

Occurrence = 0.000100

Coiled lead picks up heat from recharge operation

Occurrence = 0.008929 (E2), **Ref# 366**

Design requirement for 40 kHz, not tuned to lead coil, 99% effective

Occurrence = 0.000089 (M151)

Occurrence = 0.000093

IPG recharge coil heating from recharge operation due to 'focusing' (eddy current power loss), Occurrence = 1.00 (E0)

**Ref# 061**

Occurrence = 0.000000

Design requirement for PPC to limit power based on IPG feedback (voltage, temperature, and charge state) & design requirement for IPG to send voltage, temperature, and charge state to PPC,99% effective, Occurrence = 0.010000 (M154)

Design requirement for biocompatible temperature insulating material between PPC coil and skin contact

99% effective

Occurrence = 0.010000 (M155)

Design requirement for temperature sensor on PPC coil skin contact surface

99% effective

Occurrence = 0.010000 (M156)

Single Fault: IPG Thermister Failure, Occurrence = 0.000024 (E6), **REF # 349**

IPG / PPC MICS communication failure resulting in continuous charge, Occurrence = 0.002976 (E4)

**REF # 043,044,045,046**

Occurrence = 0.000000

IPG DFMEA 95% effective,

Occurrence = 0.000001, (M494)

Design requirement to place thermister in IPG, 99% effective

Occurrence = 0.010000 (M158)

Occurrence = 0.000000

Design requirement IPG detunes itself (with no MICS communication) when the external charger continues to deliver power despite a status message that should result in PPC stopping recharge when over temp or stuck in one phase too long, 99% effective

Occurrence = 0.000030 (M372)

Design requirement PPC hardware watchdog that shuts off charge mode, 99% effective

Occurrence = 0.000030 (M373)

Design requirement PPC shuts off charging if receiving high temperature value from IPG, IPG sends temp and PPC reacts, 99% effective

Occurrence = 0.01000

(M374)

IPG design requirement for insulative coating on battery, 99% effective Occurrence = 0.000000 (M443)

IPG hermetic seal failure leading to fluid ingress

'Single fault condition' Occurrence = 0.000002 (E7)

High current drain due to battery short, Occurrence = 0.000002 (E7)

Occurrence = 0.000000

Hand held accessories

Occurrence =

0.000089

## Excessive Heat - Part 2

PPC heating metal objects (belt buckle, coins, etc.) near or in-between PPC and IPG

Occurrence = 0.008929 (E2)

**Ref# 062**

Occurrence = 0.000004

Occurrence = 0.000026

Sensory feedback, patient will feel heat and move object, 90% effective

Occurrence = 0.000893

(M160)

To Part 1

PPC coil heat buildup during recharge, **Ref# 335, 060**

Labeling guidance to recharge over bandage, cloth material, or other means other than bare skin if heat sensation is felt, 50% effective

Occurrence =

0.000030

(M162)

Design requirement for temperature sensor on PPC recharge coil, 99% effective

Occurrence = 0.000000

(M164)

Design requirement for limited PPC recharge current, 99% effective

Occurrence = 0.000000

(M163)

IPG Design requirement to limit recharge time by enforcing maximum times in each phase and requirement for detecting battery voltage change between samples in pre-charge and constant current phases, 99% effective

Occurrence = 0.000000

(M165)

Occurrence = 0.000000

Occurrence = 0.000036

Labeling in IPG implant manual regarding placement and suturing, Occurrence = 0.000012, (M161)

Twiddler syndrome results in flipped IPG

Occurrence = 0.000024 (E6), **Ref# 261**

Other causes of flipped IPG, Occurrence = 0.000024 (E6), **Ref# 262**

Labeling guidance to keep metal objects away from recharge area, 50% effective

Occurrence = 0.004465

(M159)

Increased recharge power / heat from reduced charge efficiency

Occurrence = 0.000060

Other causes for extended time or reduced charge efficiency

Occurrence = 0.000024 (E6)

PoP single fault failure mode resulting in heat

Occurrence =

0.008929

PoP single fault failure mode resulting in heat

Occurrence =

0.008929

PoP single fault failure mode resulting in heat

Occurrence =

0.008929

PoP single fault failure mode resulting in heat

Occurrence =

0.008929

PoP DFMEA, 95% effective (M0491)

Occurrence =

0.000446

CP DFMEA, 95% effective (M493)

Occurrence =

0.000446

EPG DFMEA, 95% effective (M0494)

Occurrence =

0.000446

PFT DFMEA, 95% effective (M495)

Occurrence =

0.000446

Occurrence = 0.001786

To Part 1

Electronic encased within enclosure with air gap, 95% effective

Occurrence =

0.000089

PPC single fault failure mode resulting in heat

Occurrence =

0.008929

PPC DFMEA, 95% effective (M492)

Occurrence =

0.000446

Electronic encased within enclosure with air gap, 95% effective

Occurrence =

0.000022

## Excessive Heat – Severe

All therapy induced heat including Diathermy heat generation, RF or Microwave ablation

Occurrence = 0.000238 (E5)

**Ref# 263**

Labeling for warning not to use Diathermy, Radio frequency / microwave ablation, 50%effective

Occurrence = 0.000119

(M166)

**Excessive Heat – Severe**

Occurrence =  3 0.0001195

Severity =  4

Risk Index =  12

Occurrence = 0.0001195

IPG DFMEA, 95% effective

Occurrence = 0.050000 (M439)

Battery, hybrid short, or Current Leakage

'IPG Single fault condition' Occurrence = 1.00 (E0)

**Ref# 130**

EN45502 single fault heat testing – MERE 0331, 90% effective

Occurrence = 0.100000 (M148)

Occurrence = 0.00000050

IPG design requirement for fuse on battery power, 99% effective

Occurrence = 0.010000 (M442)

Component Support Protect terminals

Occurrence = 0.0100000 (M447)

PoP discharged to point of Lithium battery ≤ 2.0 V

Occurrence = 0.011905 (E1)

Device plugged in for recharge, probability 100%,

Occurrence = 0.011905

Design requirement, PoP will not recharge if battery ≤ 2.0V, 100%effective

Occurrence = 0.0000000

(M469)

PPC discharged to point of Lithium battery ≤ 2.0 V

Occurrence = 0.011905 (E1)

Device plugged in for recharge, probability 100%,

Occurrence = 0.011905

Design requirement, PPC will not recharge if battery ≤ 2.0V, 100%effective

Occurrence = 0.0000000

(M470)

CP discharged to point of Lithium battery ≤ 2.0 V

Occurrence = 0.011905 (E1)

Device plugged in for recharge, probability 100%,

Occurrence = 0.011905

Design requirement, CP will not recharge if battery ≤ 2.0V, 100%effective

Occurrence = 0.0000000

(M471)

EPG batteries installed backwards

Occurrence = 0.011905 (E1)

Excessive internal current, probability 100%,

Occurrence = 0.011905

Design requirement, block current flow if battery polarity reversed, 100%effective

Occurrence = 0.0000000

(M472)

## Infection - Part 1

Sterilization process validation and process control for all implantable components, 99.99% effective

Occurrence = 0.000100 (M178)

Mycobacterium contamination

Occurrence = 1.00 (E0)

**Ref# 264**

Labeling for UBD on all implantable components, 50% effective

Occurrence = 0.000012

(M176)

Components past package sterilization date

Occurrence = 0.000024 (E6)

**Ref# 010**

Labeling to operate EPG outside of sterile field, 50% effective

Occurrence = 0.000012

(M173)

Cross-patient infection by EPG

Occurrence = 0.000024 (E6)

**Ref# 258**

Labeling for single use on all implantable components, 50% effective, Occurrence = 0.000012, (M177)

Components re-used

Occurrence = 0.000024 (E6)

Ref# 258

Labeling in warnings not to use PPC on an unhealed wound, 50% effective

Occurrence = 0.004465

(M170)

Use PPC on an unhealed wound

Occurrence = 0.008929 (E2)

**Ref# 266**

Labeling to implant fully charged IPG. Delay recharging until the wound heals, 50% effective

Occurrence =

0.004465

(M171)

Labeling for use by date, 50% effective Occurrence = 0.005952 (M167)

**Infection**

Occurrence =  3 0.000599

Severity =  3

Risk Index =  9

Occurrence = 0.000020

Occurrence = 0.000599

Double entry package design (may be single or double seal) 99% effective

Occurrence = 0.000119 (M168)

Occurrence = 0.000000

Lead package damage due to:

* Storage & distribution
* Manufacturing & processing

Occurrence = 0.005952 (E3)

**Ref# 009**

Lead exposure to infectious contamination

Occurrence = 0.005952 (E3)

**Ref# 181**

Occurrence = 0.011904

Package validation 90% effective

Occurrence = 0.001190 (M169)

From Part 2

Occurrence = 0.000000

EPG Ground Pad skin contact (1-2 weeks)

Occurrence = 1.00 (E0)

**Non-Hazard Scenario**

Infection from Extended Contact - No mitigation at this time, infection considered unlikely

Occurrence = 0.000000

Design requirement for EPG to accept 10% bleach, alcohol etc. wipe-down, 50% effective (requires clinician action)

Occurrence = 0.000012

(M174)

Design requirement for screener cable to be long enough (1 meter+) to be outside sterile field, 50% effective (requires clinician action)

Occurrence = 0.000012

(M175)

Occurrence = 0.000000

From Part 3

Occurrence = 0.000000

## Infection - Part 2

Non-sterile IPG, Occurrence = 0.008929 (E2)

**Ref# 001, 002, 004, 005, 006, 007, 010**

Instructions not to use damaged package, 50% effective

Occurrence = 0.004465 (M185)

Package validation 90% effective

Occurrence = 0.000893 (M169)

Sterilization process validation and process control for all implantable components 99% effective, Occurrence = 0.000089 (M178)

Labeling for UBD on all implantable components, 50% effective, Occurrence = 0.004465 (M176)

IPG package damage due to:

* Storage & distribution
* Manufacturing & processing

Occurrence = 0.005952 (E3) **Ref# 182**

Package validation 90% effective

Occurrence = 0.001190

(M169)

Double entry package design (may be single or double seal) 99% effective

Occurrence = 0.000119

(M168)

Occurrence = 0.000000

Occurrence = 0.000000

Labeling to administer IV antibiotics and do not place IPG on skin, 50% effective, Occurrence = 0.004465 (M184)

Lead DFMEA 95% effective

Occurrence = 0.000446

(M52)

Compromise antibiotic effectiveness due to component fragments

Occurrence = 0.008929 (E2) **Ref# 008**

IPG Exposure to infectious contamination

Occurrence = 0.005952 (E3) **Ref# 003**

Occurrence = 0.000455

To Part 1

Occurrence = 0.011904

Labeling for IPG use by date, 50% effective

Occurrence = 0.002976 (M181)

Design requirement to be able to recharge IPG while in box, 99% effective

Occurrence = 0.000119

(M180)

Device on shelf too long to maintain sterilization

Occurrence = 0.005952 (E3)

**Ref# 392**

Process requirement to use sterilization date whichever is last to link with use by date, 50% effective

Occurrence = 0.002976

(M183)

Non-sterile or biologically contaminated Tunneling Tool

Occurrence = 1.0 (E0)

Design requirement for tunneling tool handle to be solid, 99% effective

Occurrence = 0.010000

(M411)

Sterilization process validation and process control for all implantable components 99% effective

Occurrence = 0.010000

(M178)

Design requirement for tunneling tool shaft to be solid, 99% effective

Occurrence = 0.010000

(M412)

Occurrence = 0.000000

Design requirement for open ended tunneling tool sheath for effective sterilization, 99% effective

Occurrence = 0.010000

(M410)

Non-sterile or biologically contaminated Stylet, stylet ‘springs out’ of package when opened and falls to non-sterile area

Occurrence = 0.005952 (E3)

Design requirement for extra stylets packaged with product, 99% effective

Occurrence = 0.000595

(M420)

Design requirement for package to hold leads such they do not ‘spring out’ when opened 99% effective

Occurrence = 0.000595

(M421)

Occurrence = 0.000000

Occurrence = 0.000009

## Infection - Part 3

Occurrence = 0.000000

To Part 1

Design requirement radio communication so programmer (CP) is outside sterile field (1 meter), 99% effective

Occurrence = 0.000000 (M172)

Cross-patient infection by use of CP

Occurrence = 0.000024 (E6)

**Ref# 265**

Labeling guidance in patient trial & system manual for PoP cleaning, 100% effective

Occurrence = 0.000000

(M476)

Cross-patient infection by PoP

Occurrence = 0.000024 (E6)

**Ref# 258**

Labeling guidance in patient system manual for PPC cleaning, 100% effective,

Occurrence = 0.000000

(M477)

Cross-patient infection by PPC

Occurrence = 0.000024 (E6)

**Ref# 258**

## Infection of Central Nervous System or Spinal Canal

Non-sterile Lead

Occurrence = 0.008929 (E2)

**Ref# 269**

Instructions not to use damaged package, 50% effective

Occurrence = 0.004465

(M185)

Sterility process control / validation 99% effective

Occurrence = 0.000089

(M186)

Occurrence = 0.000000

Labeling to administer IV antibiotics and do not place IPG on skin, 50% effective

Occurrence = 0.004465

(M184)

**Infection of Central Nervous System or Spinal Canal**

Occurrence =  1 0.000000

Severity =  4

Risk Index =  4

Occurrence = 0.000000

Labeling for use by date, 50% effective Occurrence = 0.005952

(M189)

Double entry package design (may be single or double seal) 99% effective

Occurrence = 0.000119

(M168)

Occurrence = 0.000000

Lead package damage due to:

* Storage & distribution
* Manufacturing & processing

Occurrence = 0.005952 (E3)

**Ref# 267**

Lead exposure to infectious contamination

Occurrence = 0.005952 (E3)

**Ref# 268**

Occurrence = 0.011904

Package validation 90% effective

Occurrence = 0.001190

(M169)

Labeling guidance to tilt needle to oblique angle to help bring lead more parallel with dura, 50% effective, Occurrence = 0.000012 (M427)

Lead damages dura at implant opening opportunity for infection

Occurrence = 0.000024 (E6), **Ref# 174**

Design requirement for shovel feature on introducer needle to help bring lead more parallel with dura, 99% effective

Occurrence = 0.000000 (M424)

Occurrence = 0.000000

Design requirement for smooth electrode surface, 99% effective

Occurrence = 0.000000 (M138)

Labeling guidance to start introducer needle one vertebra dorsally from ligamentum flavum target to help bring lead more parallel with dura, 50% effective, Occurrence = 0.000012 (M429)

Physician sterilizes & re-uses elevator, Occurrence = 0.000238 (E2), **Ref# 269**

Elevator tool is plastic & is not re-sterilizable 50% effective

Occurrence = 0.000119

(M458)

Elevator labeled as single use, 50% effective

Occurrence = 0.000119

(M459)

Occurrence = 0.000000

Elevator appears re-sterilizable

Lead manufacturing related pyrogen contamination

Occurrence = 1.0 (E0)

Remaining devices do not use water in the manufacturing process, 80% population, Occurrence = 0.80

Design requirement surgical lead be sonic cleaned in production with 90/10 water/alcohol solution, 99.9% effective, Occurrence = 0.000200, (M486)

Surgical lead uses water in the manufacturing process, 20% population, Occurrence = 0.20

Clean room manufacturing with no water, 99.9% effective, Occurrence = 0.000800

Occurrence = 0.001000

Bio testing to confirm insignificant level of pyrogen, 99.9% effective, Occurrence = 0.000001

(M487) (Report 1013760)

Leads not intended for intrathecal space and CSF is positive pressure so accidental puncture contamination prevented, 90% effective, Occurrence = 0.000100

Occurrence = 0.000000

## Misleading Information - Part 1

Error in impedance measurement that appears correct

Occurrence = 0.008929 (E2)

**Ref# 270**

Multi-channel stimulation causing error in impedance measurement

Occurrence = 0.008929 (E2)

**Ref# 271**

Design requirement to prevent checking impedance during multi-channel stimulation, 100% effective

Occurrence = 0.000000

(M192)

Design requirement for impedance measurement accuracy greater than just open / short, 99% effective

Occurrence = 0.000089 (M191)

Lead conductor open

Occurrence = 0.008929 (E2)

**Ref# 273**

Design requirement to check calibration at stim on (source & sink), 95% effective, Occurrence = 0.000004 (M48)

**Misleading Information**

Occurrence =  2 0.000070

Severity =  3

Risk Index =  6

Occurrence = 0.000070

DFMEA Leads 95% effective

Occurrence = 0.000004 (M52)

Occurrence = 0.000000

Open conductor shorted to another conductor

Occurrence = 0.008929 (E2)

**Ref# 186**

Occurrence = 0.000080

Open-short condition passes impedance test in error

**Ref# 336**

Labeling instructions for completing impedance check(s), 10% effective

Occurrence = 0.000893 (M369)

CP Software validation 95% effective

Occurrence = 0.000446

(M379)

True bad impedance will also set an IPG error code 99% effective

Occurrence = 0.000089

(Mxxxx)

Incorrectly display lead impedance error (false negative) on CP

Occurrence = 0.008929 (E2)

**Ref# 374**

Occurrence = 0.000000

CP Software validation, 95% effective

Occurrence = 0.000001

(M379)

Single fault: IPG error code decode error in CP

Occurrence = 0.000024 (E6)

**Ref# 375**

From Part 2

Occurrence = 0.000000

Occurrence = 0.000238 (E5)

CP dies due to low battery before date information is entered

Clinician enters incorrect implant date

CP stores date incorrectly

CP Software verification 90% effective

Occurrence = 0.0000238

(M473)

Design requirement for early shutdown of CP on low battery

90% Effective

Occurrence = 0.0000238

(M475)

Backup Battery for RTC 90% Effective

Occurrence = 0.0000238

(M474)

Occurrence = 0.000000

Incorrect ERI displayed on CP

Occurrence = 0.0000000

Incorrect date at time of implant

Occurrence = 0.000238 (E5)

Human factors testing per IEC 60601-1-6 90% Effective

Occurrence = 0.0000238

(M474)

## Misleading Information - Part 2

Mismatch between patient file data and data on CP

Occurrence = 0.005952 (E3)

**Ref# 377**

Single Fault: CP data corrupted

Occurrence = 0.000024 (E6)

**Ref# 378**

Design requirement for CP to use off-the-shelf SQL data integrity checks, 100% effective

Occurrence = 0.000000

(M382)

Design requirement for CP to display patient ID from pick list of IPGs in range, information is Name and DOB, 99% effective

Occurrence = 0.000060

(M383)

To Part 1

Occurrence = 0.000069

Software verification 90% effective

Occurrence = 0.000893

(M193)

IPG DFMEA 95% effective

Occurrence = 0.000446

(M494)

IPG Battery indication in error following implant

Occurrence = 0.008929 (E2)

**Ref# 272**

Occurrence = 0.000000

Labeling guidance to use one of multiple devices (PoP, PPC, CP) to verify low battery when indicated, 50% effective

Occurrence = 0.004465

(M194)

IPG brought out of cold storage and used before it warms to room temperature

Occurrence = 0.000238 (E5)

Battery indication in error prior to implant

Occurrence = 0.005952 (E5)

**Ref# 272**

Occurrence = 0.000009

Labeling guidance to use one of multiple devices (PoP, PPC, CP) to verify low battery when indicated, 50% effective

Occurrence = 0.002976

(Mxxxx)

Labeling guidance to ensure IPG at room temperature before charging

Occurrence = 0.002976

(Mxxxx)

## Neural Compression or Damage - Part 1

Lead electromechanical failures, Occurrence = 0.008929 (E2) **Ref# 188**

DFMEA Leads, 95% effective, Occurrence = 0.000446 (M52)

Lead punctures dura or Spinal Cord at implant, Occurrence = 0.008929 (E2) **Ref# 174**

Lead fragment left in epidural space

Occurrence = 0.000024 (E6)

**Ref# 189**

Labeling guidance on implant technique (e.g. do not back lead up when in introducer needle and stylet in place), 50% effective, Occurrence = 0.000012 (M199)

**Neural Compression or Damage**

Occurrence =  3 0.000476

Severity =  4

Risk Index =  12

Occurrence = 0.000472

Design requirement for soft lead body and rounded tip 95% effective, Occurrence = 0.000446 (M198)

Occurrence = 0.000000

Lead Anchor 99% effective, Occurrence = 0.000089 (M47)

Lead migration up or down spinal cord column (i.e. high placement – migration can cause nerve compression damage), Occurrence = 0.008929 (E2) **Ref# 192**

Clinician Manual guidance on lead implant techniques, coiling, strain relief, use of anchor, no meandering, etc. , 50% effective

Occurrence = 0.004465 (M46)

Occurrence = 0.000000

From Part 2

Occurrence = 0.0000016

Labeling guidance to confirm location in epidural space, effectiveness = 50%, Occurrence = 0.001488 (M431)

Puncture dura with introducer needle, Occurrence = 0.005952(E3)

Design requirement for ‘shoulder’ on needle to produce loss of resistance and tactile feedback when penetrating ligamentum flavum, effectiveness = 50%

Occurrence = 0.001488 (M432)

Occurrence = 0.000002

Design requirement to have ‘shovel’ feature on needle to reduce potential for dura puncture, effectiveness = 50%, Occurrence = 0.002976 (M424)

Occurrence = 0.002976

Labeling guidance to tilt needle to oblique angle (approximately 30°) with bevel of needle up prior to penetrating muscle and fascia and point to ligamentum flavum target

50% effectiveness,

Occurrence = 0.002976 (M427)

Design requirement for 2 different needle sizes to accommodate various anatomies (approximate 4” provided in original packaging with approximate 6” needle available as accessory, effectiveness = 50%, Occurrence = 0.002976 (M426)

Labeling guidance to start introduce needle one vertebra dorsally from ligamentum flavum target, effectiveness = 50%, Occurrence = 0.002976 (M429)

Labeling guidance to start introducer needle one vertebra dorsally from ligamentum flavum target, effectiveness = 50%, Occurrence = 0.004465 (M429)

Labeling guidance to tilt needle to oblique angle (approximately 30°) with bevel of needle up prior to penetrating muscle and fascia and point to ligamentum flavum target to help guide lead in path parallel to dura

50% effectiveness,

Occurrence = 0.004465 (M427)

Occurrence = 0.000000

## Neural Compression or Damage - Part 2

Labeling guidance on keeping bends in lead to a minimum and to avoid kink, replace if kinked

Occurrence = 0.004465

(M200)

Design requirement for rounded stylet tip to minimize external breach

Occurrence = 0.000089

(M201)

Stylet protruding thru the percutaneous lead coil

Occurrence = 0.008929 (E2)

**Ref# 191**

Labeling guidance on use of anchor and strain relief (lead wrap)

Occurrence = 0.000012

(M204)

Lead migration through the dura

Occurrence = 0.000024 (E6)

**Ref# 194**

Occurrence = 0.000000

Occurrence = 0.0000016

To Part 1

Lead body compresses dura or spinal cord

Occurrence = 0.005952(E3)

Varying space in the spinal column such as more space in the lumbar region compared to cervical region is knowledge that would be expected of the "learned intermediary" of the physician. Also not appropriate labeling information because a patient could have foraminal stenosis, which would affect the space in the lumbar region, effectiveness = 50%, Occurrence = 0.002976

Puncture dura with lead

Occurrence = 0.002976(E4)

Design requirement for ‘shovel’ tip on needle to help guide lead in path parallel to dura, effectiveness = 90%, Occurrence = 0.000298 (M424)

Patient feedback, can feel pressure, effectiveness = 90%, Occurrence = 0.000595

Labeling guidance to use care in epidural placement and not use excessive force after loss-of-resistance stage of needle introduction, effectiveness = 50%, Occurrence = 0.001488 (M433)

Occurrence = 0.000000

Occurrence = 0.000002

Insert elevator too far to compress dura onto spinal cord

Occurrence = 0.002976(E4)

Elevator provided with pre-curve, effectiveness = 50%, Occurrence = 0.001488 (M457)

Occurrence = 0.000000

Elevator forming tool provided for physician to adjust curve effectiveness = 50%, Occurrence = 0.001488 (M456)

Elevator metal handle design provides tactile feedback, effectiveness = 90%, Occurrence = 0.000298 (M455)

Elevator metal handle design provides tactile feedback, effectiveness = 90%

Occurrence = 0.000002

(M455)

Press on elevator too hard

Occurrence = 0.000024 (E6)

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 1

**Overstimulation – Non-Surgical Correction & Non-Permanent**

Occurrence =  1 0.000000

Severity =  2

Risk Index =  2

Occurrence = 0.041324

IPG design requirement for ‘Stim Off’ from paired PoP, PPC, or CP including PFT, 99% effective

Occurrence = 0.000413

(M206)

CP, PPC, & PoP design requirement for user button press (or touch screen) to decrement current, reducing the stim signal, 99% effective

Occurrence = 0.000413

(M207)

Occurrence = 0.009375

Design requirement for:

‘Full Stim Off’ or 5-second magnet ‘Off’: Only PPC can turn IPG stim back on from 5s storage mode (power ASIC), Note: Logic function, not processor so works if processor is corrupt.

* PPC needs to get to charge screen with unpaired MICS communication to bring IPG out of storage mode
* 2-second magnet ‘Off’: PPC, CP, PoP. magnet can turn stimulation back on

99% effective, Occurrence = 0.000413 (M85)

Occurrence = 0.021110

Occurrence = 0.000267

Occurrence = 0.000148

Occurrence = 0.000000

From

Part 2

(CLINICIAN PROGRAMMING)

From

Part 6

(PHYSIOLOGICAL)

From

Part 7

(EPG)

From

Part 5

(ENVIRONMENTAL AND OOR)

From

Part 4

(IMPEDANCE)

From

Part 3

(PATIENT PROGRAMMING-CHARGING and PoP

Occurrence = 0.010424

Occurrence = 0.000000

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 2 (Clinician Programmer)

Pre-populated values present in CP and are too high

Occurrence = 0.005952 (E3)

**Ref# 278**

Switch to new patient with same CP

Occurrence = 0.008929 (E2)

**Ref# 277**

PoP, PPC MICS paired communication design requirement, CP MICS communication by selecting from list of available serial numbers, 99% effective

Occurrence = 0.000207

(M40)

Occurrence = 0.000000

Current amplitude too high, Occurrence = 0.009375

Wrong patient is programmed to higher current because they are in range of intended patient. Multiple patients in a clinic at one time is anticipated to be common practice

Occurrence = 0.005952 (E3)

**Ref# 078**

Occurrence = 0.020692

To Part 1

Design requirement for CP to allow user to adjust rtarget, 99% effective

Occurrence = 0.000002 (E7)

(M269)

Changing to a lower rate from a clipped higher rate increases output current as IPG moves into proper performance (stops clipping).

Occurrence = 0.000238 (E5)

**Ref# 274**

Design requirement for CP user interface to acknowledge current is limited at higher rate, 99% effective

Occurrence = 0.000002 (E7)

(M210)

Occurrence = 0.000000

Clinician programs IPG to high current

Occurrence = 0.008929 (E2)

**Ref# 275**

Instructions to user via interface display and/or confirm patient name/id, 50% effective

Occurrence = 0.010346

(M216)

CP DFMEA 95% effective for surgical issues

Occurrence = 0.000446

(M493)

CP electromechanical failure resulting in loss of stim off function

Occurrence = 0.008929 (E2)

**Ref# 288**

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 3a (Patient Programmer-Charger & Pocket Programmer)

PoP, PPC Design requirement that stim increment cannot exceed clinician pre-set programmed limits, 99% effective

Occurrence = 0.010000

(M224)

Patient increments stim parameters over the limit by selecting new program, Occurrence = 1.00 (E0), **Ref# 282**

Current Amplitude too high, Occurrence = 0.021110

To Part1

Patient switches to inappropriate program

Occurrence = 1.00 (E0)

**Ref# 280**

Design requirement for original clinician settings can be restored at any time by PPC 99% effective

Occurrence = 0.010000 (M220)

Note: Only PPC can set device back on from ‘storage mode’. IPG stores default settings.

Patient returns IPG to default settings (that are too high) when not intending to do so.

Occurrence = 0.005952 (E3)

**Ref# 279**

Labeling caution for using lowest settings possible for effective treatment, since high settings may cause patient discomfort,

99% effective

Occurrence = 0.000060

(M219)

Design requirement for PPC & PoP to increment slowly regardless of how fast button is pressed, 99% effective

Occurrence = 0.000060

(M208)

Occurrence = 0.000000

Patient loses or breaks PoP

Occurrence = 0.011905 (E1)

**Ref# 281**

Design requirement for 3 methods of turning off or reducing stim (PPC, PoP, and Magnet) – each are 99% effective, assume 2 methods are available if one is lost, resulting effectiveness 99.99%

Occurrence = 0.000004

(M222)

Occurrence = 0.000004

From part 3b

Occurrence = 0.000927

Patient loses or breaks PPC

Occurrence = 0.011905 (E1)

**Ref# 281**

Occurrence = 0.035715

Patient loses or breaks Magnet

Occurrence = 0.011905 (E1)

**Ref# 281**

From part 3c

Patient puts device in storage mode via 5-second magnet whether painful stim is present or not then turns IPG on with PPC (waking device returns to default settings)

Occurrence = 1.00 (E0) **Ref# 393**

Default settings are too high, Occurrence = 0.005952 (E3)

**Ref# 394**

Occurrence = 0.005952

Occurrence = 0.000060

Patient turns painful stim off (via quick stim off, 2-second magnet, or normal menus) instead of switching programs or decrementing stim; then turns device back on, Occurrence = 0.011905 (E1) **Ref# 393**

Patient can reset to defaults using PPC, 99% effective

Occurrence = 0.000119 (M220)

Occurrence = 0.000000

Patient can switch to a different program using PoP, 99% effective

Occurrence = 0.000119 (M251)

Patient can switch to a different program using PPC, 99% effective, Occurrence = 0.000060 (M221)

Design requirement patient or clinician can switch to different program using PPC, 99% effective, Occurrence = 0.000119 (M221)

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 3b (Patient Programmer-Charger & Pocket Programmer)

To part 3a

Increase Pulse Width too fast (with same Amplitude)

Note: Program output or individual pulses

Occurrence = 0.011905 (E1)

**REF # 350**

IPG Design requirement to limit rate of Pulse Width increase regardless of user input, 99% effective

Occurrence = 0.000119

(M225)

CP, PPC Design requirement for Pulse Width decrement to go as fast as system capability, 99% effective

Occurrence = 0.000119

(M226)

CP Design requirement to lock out the ability to increase PW as default, 50% effective

Occurrence = 0.005953

(M227)

CP Design requirement for clinician settable limits on Pulse Width parameters, 50% effective

Occurrence = 0.005953

(M228)

Increase Frequency too fast (with same Amplitude)

Note: Program output or individual pulses

Occurrence = 0.011905 (E1)

**REF # 351**

PPC, CP, PoP Design requirement to limit rate of Frequency increase regardless of user input, 99% effective

Occurrence = 0.000119

(M226)

CP, PPC, Design requirement for Frequency decrement to go as fast as system capability, 99% effective

Occurrence = 0.000119

(M232)

CP Design requirement to lock out this feature as default, 50% effective

Occurrence = 0.005953

(M227)

CP Design requirement for clinician settable limits on Pulse Width parameters, 50% effective

Occurrence = 0.005953

(M228)

Occurrence = 0.000927

IPG turns off using magnet swipe instead of decrement and its turned back on or different program or PPC, PoP, CP due to pain

Occurrence = 0.005952 (E3)

**Ref# 395**

Painful stim at current setting

Occurrence = 0.005952 (E3)

**Ref# 396**

Occurrence = 0.000035

Occurrence = 0.000000

Occurrence = 0.000000

PoP DFMEA 95% effective for surgical issues

Occurrence = 0.000446

(M491)

PoP electromechanical failure resulting in loss of stim off function

Occurrence = 0.008929 (E2)

**Ref# 288**

PPC DFMEA 95% effective for surgical issues

Occurrence = 0.000446

(M492)

PPC electromechanical failure resulting in los of stim off function

Occurrence = 0.008929 (E2)

**Ref# 288**

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 3c (Patient Programmer-Charger & Pocket Programmer)

Design requirement to disable functionality of PPC, CP, PoP at safe low battery limit, 99% effective

Occurrence = 0.000119

(M79)

Increasing stimulation parameters with low battery, can’t finish

Occurrence = 0.011905 (E1)

**REF # 353**

Occurrence = 0.000036

Ambulatory overstim due to physiological reason scenario presents

Occurrence = 0.005952 (E3)

**REF # 354**

Design requirement for PoP going into low power mode (only ‘Off’ command available), 99% effective

Occurrence = 0.000000

(M236)

To part 3a

Over-shoot stim amplitude setting by double key press, key bounce, etc.

Occurrence = 0.011905 (E1)

**REF # 352**

Design requirement for CP, PoP, PPC keyed input not to get ahead of actual output (assures physiological feedback), 99% effective

Occurrence = 0.000119

(M233)

Design requirement for ‘Stim Off’ button on PoP & PPC, 99% effective

Occurrence = 0.000060

(M235)

Design requirement for PPC, CP, PoP decrease current amplitude command to proceed as fast as system capability, 99% effective

Occurrence = 0.000060

(M234)

Occurrence = 0.000119

Design requirement for PPC, CP, PoP to always display its own battery status, 99% effective

Occurrence = 0.000119

(M80)

Low battery on PoP or PPC prevents turn down

Occurrence = 0.005952 (E3)

**REF # 355**

If PoP low, PPC available or vice versa, 99% effective

Occurrence = 0.000000

(M84)

Design requirement for PPC and PoP to always display its own battery status, 99% effective

Occurrence = 0.000000

(M80)

Design requirement for CP, PoP, PPC keyed input to maximum increment rate in order not to overshoot and cause pain, 99% effective

Occurrence = 0.000119

(M371)

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000000

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 4 (Impedance)

Patient feels or has response associated with applied current for periodic or background check of active pairs

Occurrence = 0.008929 (E2)

**Ref# 283**

Design requirement for IPG to revert to low settings during impedance check. These settings are typically sub-threshold and are settable by clinician via CP, 99% effective

Occurrence = 0.000089

(M440)

Occurrence = 0.000089

Current amplitude too high

Occurrence = 0.000267

To Part 1

Patient feels or has response associated with applied current for in-office diagnostic check of ALL combinations

Occurrence = 0.008929 (E2)

**Ref# 284**

Patient feels or has response associated with applied current during impedance check while stim is occurring

Occurrence = 0.008929 (E2)

**Ref# 285**

Design requirement for IPG to revert to low settings during impedance check. These settings are typically sub-threshold and are settable by clinician via CP, 99% effective

Occurrence = 0.000089

(M440)

Labeling requirement to inform clinician they can turn stim off during impedance check, 99% effective

Occurrence = 1.0

(M441)

Occurrence = 0.000089

Design requirement for IPG to revert to low settings during impedance check. These settings are typically sub-threshold and are settable by clinician via CP, 99% effective

Occurrence = 0.000089 (M440)

Labeling requirement to inform clinician they can turn stim off during impedance check, 99% effective

Occurrence = 1.0

(M441)

Labeling requirement to inform clinician they can turn stim off during impedance check, 99% effective

Occurrence = 1.0

(M441)

Occurrence =0.000089

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 5 (Environmental And Out Of Regulation)

Design requirement for CRC check on all commands before implementing, 99% effective

Occurrence = 0.000089

(M20)

EMI/EMC

Validation Testing 95% effective

Occurrence = 0.000446

(M242)

Data corruption in wireless command resulting in erroneous high current setting

Occurrence = 0.008929 (E2)

**Ref# 063**

Occurrence = 0.000000

Current amplitude too high

Occurrence = 0.000148

To Part 1

IPG Out-Of-Regulation (OOR) operation due to Low Impedance System, Low Battery, High Rate, High Current, shorting of active electrodes, Clipping, or battery at low end of recharge cycle, regulation returns and outputs increase.

Occurrence = 0.008929 (E2)

**Ref# 022, 032, 033, 034, 036, 039 054, 079, 080, 081, 082, 146**

Design requirement for clinician set limit checking of stim values, 99% effective

Occurrence = 0.000089

(M244)

IPG & EPG Design requirement for Parameter interlocks including max stim output power, battery cutoff, impedance checks.

99% effective

Occurrence = 0.000089

(M246)

Magnetic field (EAS gate, etc.) inadvertently turns IPG on through magnet feature, Occurrence = 1.0 (E0) **REF # 356**

Design requirement magnet feature does not turn rechargeable devices on, just off. 100% effective, Occurrence = 0.000000 (M245)

Design requirement for CRC check on all commands before implementing, 99% effective

Occurrence = 0.000059

(M20)

Internal incorrect settings due to IPG internal error, Occurrence = 0.005952 (E3) **Ref# 397**

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 6 (Physiological)

To Part 1

Leads migration up or down spinal cord column due to patient movement (can be remedied by new parameter or electrode) and gets closer to nerve

Occurrence = 1.00 (E0)

**Ref# 193**

Design requirement for CP able to change to new set of electrodes by selecting another program, 90% effective, Occurrence = 0.100000 (M250)

Lead Anchor 99% effective,

Occurrence = 0.010000

(M47)

Clinician Manual guidance on lead implant techniques, coiling, strain relief, use of anchor, no meandering, etc., 50% effective

Occurrence = 0.500000 (M46)

Present current amplitude becomes too high for physiological reasons

Occurrence = 0.000000

(M254)

Patient loses PoP

Occurrence = 0.011905 (E1)

**Ref# 281**

Patient loses PPC

Occurrence = 0.011905 (E1)

**Ref# 281**

Excessive output current

Occurrence = 0.005952 (E3)

**Ref# 155**

Occurrence = 0.000142

Occurrence = 0.000000

Occurrence = 0.000000

IPG turns off using PPC, PoP, CP “stim off’ or magnet swipe instead of decrement or different program due to pain, then turns IPG back on Occurrence = 0.005952 (E3) **Ref# 398**

Painful stim at current setting, Occurrence = 0.005952 (E3) **Ref# 396**

Occurrence = 0.000035

Design requirement to reset IPG to default physician selected parameters using CP or PPC, 99% effective

Occurrence = 0.000000 (M408)

Occurrence = 0.000000

Design requirement that clinician can switch to different program using CP, 99% effective

Occurrence = 0.000000 (M250)

Design requirement patient or clinician can switch to different program using PoP, 99% effective

Occurrence = 0.000000 (M251)

Patient can switch to a different program using PoP, 99% effective

Occurrence = 0.010000 (M251)

Design requirement patient or clinician can switch to different program using PPC, 99% effective, Occurrence = 0.010000 (M221)

Design requirement patient or clinician can switch to different program using PPC, 99% effective

Occurrence = 0.000000 (M221)

## Overstimulation Non-Surgical Correction & Non-Permanent - Part 7 (External Pulse Generator)

To Part 1

Occurrence = 0.010424

Guidance instructions to disconnect cable from EPG or press Therapy Stop key 50%effective.

Occurrence = 0.004465

(M247)

Occurrence = 0.000000

IPG & EPG Design requirement for Parameter interlocks.

99% effective

Occurrence = 0.000089

(M246)

EPG Out-Of-Regulation (OOR) operation due to Low Impedance System, Low Battery, High Rate, High Current, shorting of active electrodes, Clipping, or battery change-out. On battery replacement, regulation returns and outputs increase, Occurrence = 0.008929 (E2)

**Ref# 022, 039, 079, 080, 082, 083, 106, 107,108,110**

Program left on EPG from previous patient use

Occurrence = 0.008929 (E2)

**Ref# 419**

Reduced need for stimulation (physiological)

Occurrence =

1. (E0)

**Ref# 418**

Occurrence = 0. 026787

EPG turned back on

Occurrence =

1. (E0)

**Ref# 417**

EPG off button pressed.

Occurrence = 0.008929 (E2)

**Ref# 400**

EPG disconnected from lead.

Occurrence = 0.008929 (E2)

**Ref# 401**

EPG in storage mode.

Occurrence = 0.008929 (E2)

**Ref# 402**

Occurrence = 0.026787

Design requirement EPG starts with stim off when turned on from ‘off’ or ‘storage’ mode, 99% effective, Occurrence = 0.000268 (M404)

Previous EPG (with paired PoP) settings and programs are higher than required

Probability = 50%

Occurrence = 0.004465

Occurrence = 0.000005

CP software design requirement to provide Pop-up reminder to clear all EPG data prior to use on a new patient, 50%effective.

Occurrence = 0.002233

(M407)

Labeling in User’s Manual to clear all EPG data prior to use on new patient, 50%effective.

Occurrence = 0.002233

(M406)

Occurrence = 0. 000004

Design requirement EPG screener cable can be disconnected by patient or clinician, 50% effective, Occurrence = 0.013394 (M435)

The clinician ramps up stim during trial programming.

Occurrence = 1.00 (E0)

**Ref# 276**

Patient sensory feedback or CASP, 99% effective

Occurrence = 0.010000

(M214)

Occurrence = 0. 008929

EPG cable reconnected (first several pulses are at high current), Probability = 10%, Occurrence = 0.000829

EPG in-use.

Occurrence = 1.0 (E1)

EPG Cable becomes disconnected,

Occurrence = 0.008929 (E2)

Stim voltages goes up to compensate for high impedance.

Label requirement to turn stim off before reconnecting disconnected lead, 50% effective, Occurrence = 0.000415 (M488)

## Overstimulation Surgical Correction - Part 1

Leads electromechanical failure shorting 2 active conductors or electrodes (adding current)

Occurrence = 0.008929 (E2)

**Ref# 195**

DFMEA 95% effective for surgical issues

Occurrence = 0.000004

(M256)

DFMEA 95% effective for surgical issues

Occurrence = 0.000446

(M256)

IPG electromechanical failure resulting in high output

Occurrence = 0.008929 (E2)

**Ref# 288**

Leads migration up or down spinal cord column due to patient movement (cannot be remedied by new parameter or electrode) and gets closer to nerve

Occurrence = 0.008929 (E2)

**Ref# 194**

Lead Anchor 99% effective

Occurrence =

0.000089 (M47)

Clinician Manual guidance on lead implant techniques, coiling, strain relief, use of anchor, no meandering, etc., 50% effective

Occurrence = 0.004465 (M46)

**Overstimulation – Surgical Correction**

Occurrence =  3 0.000535

Severity =  3

Risk Index =  9

Occurrence = 0.000000

Post implant weight gain brings IPG / Programmer coupling out of range (Note: Not uncommon for movement disorder therapy)

Occurrence = 0.000238 (E5)

**Ref# 041, 044**

IPG IFU Labeling on implant depth, 50% effective

Occurrence = 0.000119 (M5)

Device transitions to over stimulation state for some reason

Occurrence = 0.000238 (E5)

**Ref# 155**

Device antenna or other communication hardware failure

Occurrence = 0.000024 (E6)

**Ref# 124, 156**

Occurrence = 0.000535

Occurrence = 0.000001

Lead conductor open failure, driving IPG current output from 2 conductors to 1

Occurrence = 0.008929 (E2)

**Ref# 287**

Occurrence = 0.000000

From Part 2

Design requirement for hardware limitation of current, 20 milliamps per lead, 30 total, 99% effective

Occurrence = 0.000001

(M257)

Design requirement for individual current source for each channel, no change in current output, 99% effective

Occurrence = 0.000001

(M258)

Occurrence = 0.000080

IPG DFMEA, 95% effective

Occurrence = 0.000001

(M494)

Occurrence = 0.000000

Design requirement for:

‘Full Stim Off’ or 5-second magnet ‘Off’: Only PPC or CP can turn IPG stim back on (power ASIC)

PPC needs to get to charge screen with unpaired MICS communication

2-second magnet ‘Off’: PPC, CP, PoP can turn IPG back on

, 99% effective

Occurrence = 0.000002 (M85)

No Mitigation

Occurrence = 0.000000

(M0)

Occurrence = 0.000000

## Overstimulation Surgical Correction - Part 2

Clinician over tightens setscrew to point of shorting conductors

Occurrence = 0.008929 (E2)

**Ref# 290**

Design requirement for torque limit wrench, 99% effective

Occurrence = 0.000089

(M94)

Occurrence = 0.000089

High current based on electrode used due to header-contact miss-alignment

Occurrence = 0.008929 (E2)

**Ref# 048**

Clinician software programmed limits and interlock, 99% effective

Occurrence = 0.000089

(M263)

Design requirement for charge current limit stored in IPG, 99% effective

Occurrence = 0.000089

(M262)

Occurrence = 0.000000

To Part 1

## Overstim – Permanent Damage

**Overstimulation – Permanent Damage**

Occurrence = 0 0.000000

Severity =  4

Risk Index =  0

No single- fault condition producing overstimulation of both an intensity and duration long enough to cause permanent damage has been identified.

While the intensity aspect is feasible via a single fault condition, the duration aspect is negated by the fact that there are multiple paths to turn off stimulation (both via radio and via hardware based magnet switch) as well as finite battery life. Those scenarios are considered in the “overstim - surgical correction required” hazard.

## DC Offset or Leakage - Charge Imbalance or DC Leakage - Part 1

Charge Imbalance **Ref#** **072**

Inactive channel cross talk received

Occurrence = 0.008929 (E2)

**Ref# 25**

**DC Offset or Leakage - Charge imbalance or DC leakage**

Occurrence =  4 0.002976

Severity =  2

Risk Index =  8

Multi lead configuration, programming (high rates, imbalanced, infinite pulse), etc.

Occurrence = 0.008929 (E2)

**Ref# 068, 069, 367**

Occurrence = 0.000208

Corrupted data

Occurrence = 0.000238 (E5)

**Ref# 286**

Design requirement for software numerical check of RAM and NVRAM that is used, 99% effective

Occurrence = 0.000000 (M266)

Occurrence = 0.000298

Design requirement for adjustable Rtarget

Occurrence = 0.000119

(M269)

Changing to a lower rate increases output current as IPG moves to intended performance (stops clipping)

Occurrence = 0.000238 (E5)

**Ref# 365**

Occurrence = 0.000000

High stim frequency compromises stim signal recovery phase

Occurrence = 1.0 (E0)

**Ref# 403**

IPG Design requirement for absolute frequency set by lockout (Prevents encroachment on stim-recovery-phase), 100% effective

Occurrence = 0.000000 (M279)

Occurrence = 0.002978

Cross Talk

Cross-Channel Current Imbalance

Same Channel Current Imbalance

IPG Design requirement for capacitively coupled outputs, 99.9993% effective. Output capacitor component failure rate = 0.000007 (MIL-217 estimate, assuming ≤ 6pF and 24 opportunities to fail0.999993^24 = 0.999832)

Occurrence = 0.000168 \* 0.000298 = 0.000000

Occurrence = 0.000000, (M275)

Occurrence = 0.000002

Occurrence = 0.000000

Design requirement for pulse guard, 99% effective

Occurrence = 0.0000000

(M267)

Same channel output current control out of calibration

Occurrence = 0.008929 (E2)

**Ref# 23**

Design requirement to check calibration at stim on (source & sink), 99% effective

Occurrence = 0.000089

(M48)

Cross channel output current control out of calibration

Occurrence = 0.008929 (E2)

**Ref# 24**

Design requirement to check calibration at stim on (source & sink), 99% effective

Occurrence = 0.000089

(M48)

Design requirement for charge balance correction phase, 99% effective, Occurrence = 0.000090 (M277)

Occurrence = 0.009018

From Part 2

DC leakage **Ref# 144**

## DC Offset or Leakage - Charge Imbalance or DC Leakage – Part 2

Design requirement for capacitively coupled outputs, 99.9993% effective. Output capacitor component failure rate = 0.000007 (MIL-217 estimate, assuming ≤ 6pF and 24 opportunities to fail, 0.999993^24 = 0.999832)

Occurrence = 0.000168 \* 0.009375 = 0.000002

(M275)

ESD damage during implant (shock path from case to hybrid)

Occurrence = 0.008929 (E2)

**Ref# 052, 292**

Occurrence = 0.002978

Occurrence = 0.009375

IPG DFMEA, 95% effective

Occurrence = 0.000446

(M494)

Diathermy, Defib, or Cautery induced output stage failure

Occurrence = 0.008929 (E2)

**Ref# 295**

Labeling guidance to avoid or limit exposure to diathermy, defib and cautery, 50% effective

Occurrence = 0.004465

(M271)

Design requirement for IPG to have high voltage (defib) protection circuitry in output circuits, 99% effective

Occurrence = 0.000089

(M272)

Occurrence = 0.000000

Interaction with other implanted IPGs resulting in DC current on lead system

Occurrence = 0.005952 (E3)

**Ref# 291**

Component failure modes (other than output capacitors) leading to DC leakage such as ASIC failure mode where effect is 'DC leakage', discrete component failure, etc.

Occurrence = 0.008929 (E2)

**Ref# 052, 294**

Design requirement for high voltage protection circuitry on ASIC, 100% effective

Occurrence = 0.000089

(M273)

Charge imbalance caused by overshoot, undershoot, slew rate, clipping, etc.

Occurrence = 0.008929 (E2)

**Ref# 051**

Labeling guidance on precautions for other device interaction, 50% effective

Occurrence = 0.002976

(M276)

To Part 1

Clinician programs output of IPG to a set of non-balanced anodes / cathodes

Occurrence = 1.0 (E0)

CP Software design requirement anodes and cathodes are required to balance, programmed imbalance not allowed, software adjusts values to assure balance,100% effective

Occurrence = 0.0

(M276)

## Excess Charge Density or Current Density - Part 1

**Excess Charge Density or Current Density**

Occurrence =  3 0.000225

Severity =  3

Risk Index =  9

Wider pulse widths

Small discharge area

**Ref# 337**

Lead conductor fracture

Occurrence = 0.008929 (E2)

**Ref# 021, 196**

Inner lead insulation breach

Occurrence = 0.008929 (E2)

**Ref# 196**

Occurrence = 0.000001

Labeling guidance to avoid MRI, labeling more than 50% effective as MRI warning is industry standard, Occurrence = 0.000002

(M286)

MRI exposure

Occurrence = 1.00 (E0)

**Ref# 056**

Leads implanted in epidural space and do not directly contact nerves, 50% effective

Occurrence = 0.00223

(M288)

Occurrence = 0.000000

Induced current on the system

Varying magnetic field induces current in lead system

Occurrence = 1.00 (E0)

**Ref# 297**

Occurrence = 1.0

Occurrence = 0.009288

Occurrence = 0.000240

Design requirement for IPG to measure for high lead impedance 1/day, 90% effective

Occurrence = 0.000619

(M281)

Design requirement for IPG to self-check 1/day impedance circuit functionality 90% effective

Occurrence = 0.000619

(M282)

Occurrence = 0.000000

Design requirement for CP to have electrode 'health check' trend data capability at each clinical visit, 30% effective

Occurrence = 0.000433

(M283)

Design requirement for CP and PPC to report impedance-related system errors, 50% effective

Occurrence = 0.003095

(M280)

Occurrence = 0.006191

lead contact surface reduction due to corrosion, non-parallel surgical lead contact, non-uniform tissue interface, tissue reaction, scar tissue, etc.

Occurrence = 0.000238 (E5)

**Ref# 015, 016**

Labeling guidance on proper use and location of implanted leads, 50% effective

Occurrence = 0.000119

(M284)

Off-label use on tissue other than epidural surface

Occurrence = 0.000238 (E5)

**Ref# 296**

High programmed pulse width of IPG

Occurrence = 0.008929 (E2)

**Ref# 298**

xPG Hardware / Firmware failure resulting in excess current, voltage, or pulse width

Occurrence = 0.008929 (E2)

**Ref## 073, 074, 075, 141**

Occurrence = 0.000448

Occurrence = 0.009048

High current output

Excessive pulse width

High programmed amplitude (CP, PoP, PPC) exceeds current density limits

Occurrence = 0.011905 (E1)

**REF #019**

Design requirement for Clinician software to interlock and limit Amplitude / Pulse Width / Frequency combination to a safe threshold. Information stored on IPG from the CP includes lead information. Lead information follows patient, not CP. CP is only device that can change charge density limits. Software setting, therefore, 100% effective, Occurrence = 0.000000 (M287)

From Part 2

xPG DFMEA, 95% effective

Occurrence = 0.000446 (M494)

Lead DFMEA, 95% effective, Occurrence = 0.000001

(M50)

Design requirement for current limit set by CP and based on lead model. Resulting current limit and Lead model are stored in IPG, 99% effective, Occurrence = 0.000119, (M285)

Occurrence = 0.000080

Outer lead insulation breach

Occurrence = 0.008929 (E2)

**Ref# 196**

Clinician nicks lead during implant

Occurrence = 0.005952 (E3)

**REF # 357**

Occurrence = 0.006190

## Excess Charge Density or Current Density - Part 2

Design requirement to display picture of lead on CP, can confirm with card in lead packaging, 99% effective

Occurrence = 0.000000 (M292)

Programmed electrode smaller than expected (paddle lead has different size contacts)

Occurrence = 0.000238 (E5)

**Ref# 300**

Contact misalignment enough to move or bridge current to different electrode

Occurrence = 0.000002 (E7)

**Ref# 289**

Setscrew shorting conductor

Occurrence = 0.000238 (E5)

**Ref# 301**

Clinician software programmed limits and interlock, 99% effective

Occurrence =0.000000 (M291)

Design requirement for lead model stored in IPG (originates from pick list in CP); CP sets limits based on lead model pulled from IPG, 99% effective

Occurrence =0.000000 (M262)

Occurrence = 0.000000

Shorted conductor with-in IPG header

Occurrence =0.000014

(M290)

IPG DFMEA 95% effective

Occurrence =0.000012

(M494)

Conductive fluid ingress from insulation failure, etc.

Occurrence =0.000238 (E5)

**REF # 358**

Occurrence = 0.000000

Occurrence = 0.000014

To Part 1

Design requirement for torque limiting wrench, 99% effectiveness

Occurrence =0.000002

(M265)

Design requirement for visual alignment indication, 50% effectiveness

Occurrence =0.000002

(M289)

Occurrence = 0.000004

## Toxicity

System Bioincompatibility materials

Occurrence = 0.011905(E1)

**Ref# 197**

Biocompatibility testing per ISO 10993 (all devices), 99.9% effective

Occurrence = 0.000012

(M294)

Damage to IPG exposes internal materials to the body

Occurrence = 0.000024 (E6)

**Ref# 302**

IPG DFMEA 95% effective

Occurrence = 0.000001

(M494)

Failure of IPG exposes internal materials

Occurrence = 0.000024 (E6)

**Ref# 303**

IPG DFMEA 95% effective

Occurrence = 0.000001

(M494)

Inadvertently advance lead into intrathecal space

**Occurrence = 0.001**

Design requirement perc lead has non-sharp tip, 99.9% effective

Occurrence = 0.001000

(M296)

**Toxicity**

Occurrence =  1 0.000002

Severity =  4

Risk Index =  4

Occurrence = 0.000002

Design requirement for biocompatible body contact material selection, 99% effective

Occurrence = 0.000119

(M295)

Occurrence = 0.000000

Design requirement for introducer needle to have curved tip (resist puncture and gives tactile feedback) environment, 95% effective

Occurrence = 0.050000

(M297)

Occurrence = 0.000000

Label guidance to introduce lead at angle, 50% effective

Occurrence = 0.050000

(M?)

Lead in contact with CSF

Occurrence = 0.000000

Occurrence = 0.000000

Bacterial cell fragments present on body contact surface

Occurrence = 0.10

Design requirement for product built in a controlled environment, 95% effective

Occurrence = 0.00500

(M297)

Occurrence = 0.000250

Process FMEA for IPG & leads for clean final parts, 95% effective

Occurrence = 0.005000

(M298)

Endotoxin present on device

Occurrence = 0.000250

## Trauma - Part 1

Labeling guidance on tunneling technique, 50% effective

Occurrence = 0.004465

(M86)

Broken tunneling tool during procedure

Occurrence = 0.008929 (E2)

**Ref# 205**

Design requirement for 2 anchor PTS 99% effective, Occurrence = 0.000060 (M300)

Suture tearing tissue at IPG anchor site

Occurrence = 0.005952 (E3) **Ref# 305**

**Trauma**

Occurrence =  3 0.000410

Severity =  3

Risk Index =  9

Lead segment left in patient

Occurrence = 0.000024 (E6)

**Ref# 200**

No mitigation

Occurrence = 0.000024 (M0)

Prolonged surgery from dislodging the lead during reverse tunneling process; Occurrence = 0.000238 (E5) **Ref# 199**

Labeling guidance on tunneling technique, 50% effective, Occurrence = 0.000119 (M86)

Occurrence = 0.000410

Tunneling tool DFMEA, 95% effective

Occurrence = 0.000446

(Mxxxx)

Occurrence = 0.000020

From

Part 2

Occurrence = 0.000135

Labeling guidance on dressing screening cable, 50% effective

Occurrence = 0.008929 (M302)

Under ambulatory conditions, screening cable catches on something and pulls stim lead out

Occurrence = 0.008929 (E2) **REF # 359**

Design requirement for maximum disconnect force between screener cable and EPG, 99% effective, Occurrence = 0.000179 (M303)

Occurrence = 0.000002

Under ambulatory conditions, EPG is dropped

Occurrence = 0.008929 (E2)

**REF # 360**

Occurrence = 0.017858

Screener cable migrates or pulls lead out

Labeling guidance to make incision on skin prior to using tunneling tool, 50% effective

Occurrence = 0.500000

(M422)

Rounded tunneling tool Tip

Tactile feedback (does not puncture skin), 99.99% effective

Occurrence = 0.000100

Occurrence = 0.000050

Does not puncture skin, blunt trauma

Occurrence = 1.000000 (E0)

Design requirement for rounded tunneling tool tip, 99% effective

Occurrence = 0.000059

(M407)

Tunneling tool puncture through skin prior to reaching target, Occurrence = 0.002976 (E4)

Design requirement for formable tunneling tool shaft, 99.99% effective

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.005952

Tunneling tool punctures organ or vessel

Occurrence = 0.002976 (E4)

Labeling guidance on tunneling procedure, 50% effective

Occurrence = 0.002976

(M86)

From

Part 3

Occurrence = 0.000000

## Trauma – Part 2

Stylet at implant protrudes thru lead & damages tissue

Labeling guidance not to use system components if dropped or damaged or if package is damaged, 50% effective

Occurrence = 0.004465

(M304)

Sharp edges on components due to damage or design or processing, Occurrence = 0.008929 (E2) **Ref# 027, 095, 118, 119, 204**

IPG, Lead, DFMEA 95% effective

Occurrence =

0.000446

(M494, M52)

EN-45502, ISO 14708-1 requirement testing, 95% effective

Occurrence = 0.000446

(M305)

Occurrence = 0.000000

Occurrence = 0.000000

Back and forth stylet motion at implant, Occurrence = 0.008929 (E2) **Ref# 191,202**

Torturous bend in lead at implant, Occurrence = 0.008929 (E2) **Ref# 306**

Labeling guidance to keep bends in lead to a minimum and not to use back and forth motion in introducer needle, 50% effective

Occurrence =

0.000085 (M199)

Occurrence = 0.000135

Occurrence = 0.000080

To Part 1

IPG, Lead, Guidewire, Design requirement no sharp edges, 99% effective

Occurrence =

0.000089

(M38)

Design requirement for tight coil winding in primary lumen ⇒ large bend radius and small opening for stylet 99%effective, Occurrence = 0.000002 (M418)

Design requirement for introducer needle to have support for lead at bend (ie ‘shovel’ feature), 99% effective, Occurrence = 0.000089 (M417)

Occurrence = .000169

Sharp radius lead bend at exit of introducer needle, Occurrence = 0.008929 (E2)

Stylet protrudes through lead tip, Occurrence = 0.008929 (E2)

Occurrence = 0.000089

Design requirement that lead body tip is closed & ‘stretches’ to accommodate push by stylet 99%effective

Occurrence = 0.000089 (M419)

Surgical lead stylet provides column strength, 90% effective

Occurrence = 0.000023

(M453)

Surgical lead placed in wrong location

Occurrence = 0.000238 (E6)

Elevator design: all edges radiused, no sharp edges, 90% effective

Occurrence = 0.000023

(M454)

Cut tissue with edges of elevator

Occurrence = 0.000238 (E6)

## Trauma – Part 3

Occurrence = 0.000000

To Part 1

Design requirement for no sharp edges on PPC, 99% effective, Occurrence = 0.010000, (M479)

Sharp Edge on PPC

Occurrence = 1.0 (E1)

Sharp Edge on EPG

Occurrence = 1.0 (E1)

Design requirement for no sharp edges on EPG, 99% effective, Occurrence = 0.010000, (M481)

Sharp Edge on CP

Occurrence = 1.0 (E1)

Design requirement for no sharp edges on CP, 99% effective, Occurrence = 0.010000, (M480)

Sharp Edge on PoP

Occurrence = 1.0 (E1)

Design requirement for no sharp edges on PoP, 99% effective, Occurrence = 0.010000, (M478)

60601 testing, 99% effective of PPC, Occurrence = 0.010000, (M319)

60601 testing, 99% effective of EPG, Occurrence = 0.010000, (M319)

60601 testing of CP, 99% effective, Occurrence = 0.010000, (319)

60601 testing of PoP, 99% effective, Occurrence = 0.010000, (M319)

Sharp Edge on Elevator tool

Occurrence = 1.0 (E1)

Design requirement for manufacturing process to be used that does not produce sharp edges:

* Passing Elevators are cut to final physical shape with a “Photo Electrochemical Etching process”

1. Parts are masked with photo emulsion on both sides.
2. Exposed to electrochemical etching process. (unmasked metal areas are etched away)
3. Removing photo emulsion.
4. Re-Exposed to electrochemical etching process to remove sharp edges

* This process employs “Edge effect” where there is higher current density at the sharp corners than at flat area, therefore, edge material is removed and rounded.

100% effective, Occurrence = 0.000000, (M489)

Component inspection requirement to confirm no sharp edges, 90% effective, Occurrence = 0.100000, (M490)

Occurrence = 0.000000

Occurrence = 0.000000

Labeling guidance on safe use of elevator tool, effectiveness = 50%, Occurrence = 0.50000, (M491)

Occurrence = 0.000000

Design requirement for rounded guidewire tip, 99% effective

Occurrence = 0.000059

(Mxxxx)

Guidewire puncture through skin prior to reaching target, Occurrence = 0.002976 (E4)

Design requirement for guidewire to be flexible, 99.99% effective

(Mxxxx)

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.005952

Guidewire punctures organ or vessel

Occurrence = 0.002976 (E4)

Labeling guidance on use of guidewire, 50% effective

Occurrence = 0.002976

(Mxxxx)

## Electrical Shock - Part 1

EMI rectified on lead system, e.g. EAS

Occurrence = 0.000238 (E5)

**Ref# 207**

Labeling precautions to stay away from EMI sources, 50% effective

Occurrence = 0.000119

(M18)

**Electrical Shock**

Occurrence =  3 0.000877

Severity =  2

Risk Index =  6

Design requirement for touch proof pins on EPG screener cable, 99% effective

Occurrence = 0.000002

(M321)

EPG screener cable contacting mains power

Occurrence = 0.000238 (E5)

**Ref# 208**

External Pulse Generator (EPG)

Lead System

EPG patient leakage current

Occurrence =1.00 (E0)

**Ref# 309**

60601 safety testing, 95% effective

Occurrence =

0.050000

(M319)

Occurrence = 0.000500

Occurrence = 0.000877

Labeling in precautions to avoid EMI, 50% effective

Occurrence = 0.000119

(M18)

Electromagnetic field from general sources picked up on implanted stim system

Occurrence = 0.000238 (E5)

**Ref# 308**

Labeling in precautions to avoid EAS gate edges, to walk through, and not to stand in or near, 50% effective

Occurrence = 0.500000, (M318)

Electromagnetic field from electronic article surveillance (EAS) gate picked up on implanted stim system

Occurrence = 1.00 (E0), **Ref# 247**

Occurrence = 0.000288

Design requirement for IPG to have high voltage (defib) protection circuitry in output circuits, 99% effective

Occurrence = 0.000002 (M272)

Current on lead system from defib shock

Occurrence = 0.000238 (E5)

**Ref# 304**

Labeling guidance to avoid or limit exposure to diathermy, defib and cautery, 99% effective

Occurrence = 0.000002

(M271)

Occurrence = 0.000000

From Part 2

Occurrence = 0.000089

Design requirement for filtering capacitors, 99% effective

Occurrence = 0.010000

(M12)

Design requirement for IPG to have high voltage (defib) protection circuitry in output circuits, 99% effective, Occurrence = 0.010000, (M272)

Occurrence = 0.000050

Coiled lead in pocket picks up current during recharge operation

Occurrence = 1.0

DVT to confirm stimulation current output is within specified requirements during recharge, 100% effective

Occurrence = 0.00

(M467)

Design requirement for safe EPG leakage current on outputs, 99% effective, Occurrence =

0.010000, (M320)

Occurrence = 0.000500

Design requirement for EPG screener cable pull out force, 99% effective

Occurrence = 0.000002

(M303)

Occurrence = 0.000000

## Electrical Shock - Part 2

Labeling to avoid recharging during lightning storm in user guide, 50% effective

Occurrence = 0.000012

(M324)

Use the AC powered PPC, CP, PoP while in water

Occurrence = 0.000024 (E6)

**Ref# 312**

60601 safety testing 99% effective, Occurrence = 0.00089 (M319)

Occurrence = 0.000000

Occurrence = 0.000089

CP, PPC, PoP, EPG IEC 60601 safety testing, 95% effective

Occurrence = 0.000298

(M323)

Design requirement for inductive power coupling for IPG recharge. 99% effective

Occurrence = 0.000060

(M322)

Patient contact with mains power through PPC, Occurrence = 0.005952 (E3)

PPC, CP, PoP

Occurrence = 0.000000

60601 safety testing 99% effective, Occurrence = 0.000089, (M319)

Clinician leakage current all causes (PPC, CP, PoP), Occurrence = 0.008929 (E2), **Ref# 310**

Occurrence = 0.000000

Use the AC powered PPC, CP, PoP during a lightning storm

Occurrence = 0.000024 (E6)

**Ref# 311**

PPC, CP, PoP Recharger leakage current all causes, e.g. battery voltage stepped up

Occurrence = 0.008929 (E2)

**Ref# 071**

To Part 1

EN IEC 60601 safety testing checks for leakage current and insulation protection, 95% effective

Occurrence = 0.000298

(M323)

Design requirement PPC, CP, PoP accessible parts protected by basic insulation, 99% effective

Occurrence = 0.000060

(M327)

Single fault / misuse condition: Patient compromises electrical insulation when using PPC, CP, PoP, Occurrence = 0.005952 (E3) **Ref# 361**

Occurrence = 0.000000

60601 safety testing 99% effective (same as CP)

Occurrence = 0.000000

(M319)

Occurrence = 0.000000

Labeling to avoid water during recharge in user guide, 50% effective

Occurrence = 0.000000

(M325)

PPC, CP, PoP, design requirement for safe leakage current, 99% effective, Occurrence = 0. 000089, (M482)

Occurrence = 0.000000

Design requirement recharger is transformer isolated from mains power with 60601 compliant recharger, Occurrence = 0.000089 (M483)

Occurrence = 0.000000

Occurrence = 0.000000

## Unintended Effect - Part 1

EMI emissions & immunity testing per 60601 for all external Programmers and Chargers, 95% effective

Occurrence = 0.000001 (M323)

IPG Stim or CP, PPC, EPG, PoP telemetry output (EMI) interferes with telemetry or electronic equipment from outside company

Occurrence = 0.000024 (E6) **Ref# 115**

Incompatibility with other implanted company IPGs

Occurrence = 0.005952 (E3)

**Ref# 313**

Device compatibility testing with other devices with-in the company IPGs, no other devices at this time, 100% effective

Occurrence = 0.0

(M339)

Unknown off-label use

Occurrence = 0.005952 (E3) **Ref# 315**

Labeling indications for use, 50% effective

Occurrence = 0.002976 (M338)

Lead Anchor, 99% effective

Occurrence = 0.000000 (M47)

Lead migration / dislodgement

**Unintended Effect**

Occurrence =  1 0.000000

Severity =  3

Risk Index =  3

Users confused by Icons

Occurrence = 0.008929 (E2)

**Ref# 317**

Icons defined in manuals, 50% effective

Occurrence = 0.004465

(M341)

Device Compatibility

Validation Testing (MICS radio), 95% effective

Occurrence =

0.000000

(M336)

FW DVT, 95% effective

Occurrence =

0.000000

(M337)

EMI/EMC

Validation Testing, 95% effective

Occurrence =

0.000000

(M335)

MICS communication error or corruption, intended IPG altered in an unintended way, or altering a device not intended to alter, Occurrence = 0.000024 (E6) **Ref# 316**

Occurrence = 0.000000

Off-target stim

Occurrence = 0.000000

lead DFMEA 95% effective

Occurrence = 0.000001 (M52)

Patient labeling to not manipulate or twiddle IPG, 50% effective

Occurrence = 000012

(M329)

IPG suture holes to anchor IPG in place, 95% effective

Occurrence = 0.000000 (M328)

Twiddler syndrome

Occurrence = 0.000024 (E6)

**Ref# 261**

A Lead insulation breach

Occurrence = 0.000024 (E6)

**Ref# 196**

Broken conductor

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000000

Header / lead capability for visual confirmation of alignment, 50% effective

Occurrence = 0.000119 (M332)

Contacts off by one or 2, etc. in header

Occurrence = 0.000238 (E5)

**Ref# 049**

Setscrew tactile feedback to clinician, setscrew not stopped by contact and continues into connector, 50% effective, Occurrence = 0.000119

Occurrence = 0.000000

PoP, PPC MICS paired communication design requirement, CP MICS communication by selecting from list of available serial numbers, 99% effective

Occurrence =

0.000000

(M40)

Occurrence = 0.013641

From Part 2

Occurrence = 0.006232

Probability conductor pair in use has 1 or both insulations breached, Occurrence = 0.000048 (M330)

See note below

Note: Statistic involves pairs with-in a set of 8 and is more complicated than can be depicted in a fault tree. Calculation is as follows:

Using 2 random conductors out of a set of 8, chance one or both are failed if the chance of a single conductor failure is 0.000024, statistic is:

­nPk

where

n = number of opportunities = 2

k = number of occurrences = 1 and 2

p = probability of an occurrence = 0.000024(E6)

q = 1 - p

Probability of no failures = 2P0 = 0.999952

Probability of 1 of the 2 conductors failing = 2P1 = 0.000048

Probability of both conductors failing = 2P2 = 0.000000

Probability of 1 or 2 failures = 2P1 + 2P2 or 1 - 2P0 = 0.000048

IPG design requirement for ‘Stim Off’ from paired PoP, PPC, or CP, 99% effective, Occurrence = 0.000140 (M206)

CP, PPC, & PoP design requirement for user button press to decrement current, reducing the stim signal, 99% effective

Occurrence = 0.000140 (M207)

Design requirement for ‘Full Stim Off’ or 5-second magnet ‘Off’: Only PPC can turn IPG stim back on (power ASIC). PPC needs to get to charge screen with unpaired MICS communication. magnet swipe ‘Off’: PPC, CP, PoP can turn IPG back on, 99% effective Note: Logic function, not processor so works if Processor is corrupt, Occurrence = 0.000140, (M85)

Occurrence = 0.000000

From Part 3

Occurrence = 0.00006

Lead strain relief (lead wrap in pocket), 90% effective

Occurrence = 0.000002 (M331)

Design requirement for CRC check on all commands before implementing, 99% effective

Occurrence = 0.000004

(M20)

## Unintended Effect - Part 2

Labeling in language unknown or not useable by user who uses anyway, Occurrence = 0.000024 (E6) **Ref# 319**

For CE countries, languages are per AIMDD for US English. Non-English US not covered, 50% effective

Occurrence = 0.000012 (M347)

Screening cable is connected via opposite polarity to EPG port

Occurrence = 1.00 (E0) **Ref# 211**

Labeling guidance for proper EPG screener cable connection

Occurrence = 0.500000

(M344)

Keyed EPG screening cable connection, 100% effective

Occurrence = 0.000000

(M343)

Occurrence = 0.000000

In multiple CP – multiple-IPG situation, attempting to program IPG with wrong CP or different CP or vice versa

Occurrence = 0.008929 (E2) **Ref# 371**

Human Factors Testing 50% effective

Occurrence = 0.005953

(M342)

Recharging using non-company charging equipment

Occurrence = 0.000024 (E6)

**Ref# 318**

Recharging near flammable or explosive atmospheres

Occurrence = 0.008929 (E2)

**Ref# 087**

Labeling in PPC and IPG user guide to use only specified equipment, 50% effective

Occurrence = 0.000000

(M345)

Labeling in recharging user guide to avoid flammable atmospheres, 99% effective

Occurrence = 0.000089

(M346)

Occurrence = 0.006232

To Part 1

Clinician changes parameters that cause unintended effect

Occurrence = 0.011905

(E1)

**Ref# 244**

Non-company charging equipment couples with IPG and produces current on lead system

Occurrence = 0.011905 (E1)

**Ref# 318**

Occurrence = 0.000000

Design requirement for hardware ID number and patient ID confirm and session based programming for all clinician programming action, 99% effective

Occurrence = 0.000089 (M349)

PoP, PPC MICS paired communication design requirement, CP MICS communication by selecting from list of available serial numbers, 99% effective

Occurrence = 0.000089 (M40)

Attempting to program IPG with wrong PPC or PoP

Occurrence = 0.008929 (E2) **Ref# 370**

Design Requirement for CP to display program status:

* Downloaded or not
* Saved or not

99% effective

Occurrence = 0.000060

(M348)

Programs set in operating room or clinic do not get properly loaded into PoP or PPC

Occurrence = 0.005952 (E3)

**Ref# 376**

Labeling guidance to:

* Verify programming on PoP & PPC
* Read back what is currently saved
* Print report of changed and current information

50% effective

Occurrence = 0.002976

(M348)

Occurrence = 0.000000

CP dies from low battery before completing programming (mid-way through)

Occurrence = 0.000024 (E6)

**Ref# 378**

CP design requirement it can operate while charging, 99% effective

Occurrence = 0.000000

(M384)

Physician labeling guidance to read and verify commands, 50% effective

Occurrence = 0.000012

(M387)

CP design requirement for IPG battery status indicator to flash when IPG battery is low, 99% effective

Occurrence = 0.000000

(M386)

IPG design requirement it does not store data unless full, valid, command received, 99% effective

Occurrence = 0.000000

(M385)

Occurrence = 0.000000

## Unintended Effect - Part 3

Set program parameters before connecting leads to EPG

Occurrence = 0.000024 (E6)

**Ref# 381**

IPG programmed (by CP) lead configuration different from actual lead configuration

Occurrence = 0.000024 (E6)

**Ref# 379**

Occurrence = 0.00006

To Part 1

Design requirement for EPG to check 2x12 or 3x8 cable connection before starting, 99% effective

Occurrence = 0.000089

(M389)

Connect programmed EPG to leads, 25% probability

Occurrence = 0.000006

(M405)

Use previous patients EPG parameters on new patient

Occurrence = 0.008929 (E2)

**Ref# 382**

Labeling guidance to clear EPG before use, 50% effective

Occurrence = 0.004465

(M390)

Occurrence = 0.000000

Occurrence = 0.000000

EPG programmed (by CP) lead configuration different from actual lead configuration

Occurrence = 0.000024 (E6)

**Ref# 380**

Design requirement for CP to link to specific IPG / EPG serial number, 99% effective

Occurrence = 0.000089

(M388)

Software requirement EPG automatically clears data on a new patent, 100% effective

Occurrence = 0.004465

(M391)

Long-time to change out battery

Occurrence = 0.00002 (E7)

**Ref# 387**

Labeling guidance to assure EPG has new batteries to start, and is cleared of previous data, 50% effective

Occurrence = 0.000001

(M400)

Damage insulation or conductor of previously implanted lead with next implanted lead (2nd or 3rd introducer needle damages first lead), Occurrence = 0.002967 (E4) **Ref# 387**

Labeling caution that placing needles too close to each other may result in lead damage from an adjacent needle tip, 50% effective, Occurrence = 0.001484 (M423)

Occurrence = 0.000002

Labeling guidance to start introducer needle to the right, left, or one vertebra down from original implant location, 50% effective, Occurrence = 0.001484 (M429)

From Part 4

[Occurrence = 0.000002](#_Hlk323888899)

## Unintended Effect - Part 4

To Part 3

Design requirement for identification of each IPG bore, 50% effective

Occurrence = 0.08375

(M449)

Programming a lead when intending to program a different lead, probability = 10%,

Occurrence = 0.075

Labeling guidance to confirm lead location using fluoro, 50% effective

Occurrence = 0.08375

(M450)

Occurrence = 0.000002

Programming a lead when intending to program a different lead, probability = 40%,

Occurrence = 0.1

Design requirement for colored lead flags for identification, 90% effective

Occurrence = 0.01675

(M448)

Patient provides feedback during trial stimulation, 90% effective

Occurrence = 0.01675

(M451

Use 2-bore connector IPG, 75% of sales volume

Occurrence = 0.75

Use 3-bore connector IPG, 25% of sales volume

Occurrence = 0.25

Occurrence = 0.167500

## Unintended Revision Surgery - Part 1

Label validation 95% effective, Occurrence = 0.000446 (M353)

Mislabeled product

Occurrence = 0.008929 (E2) **Ref# 216**

Packaging validation 90% effective, Occurrence = 0.000893 (M169)

Shipping damaged product

Occurrence = 0.008929 (E2) **Ref# 214**

Lead electromechanical failure at implant

Occurrence = 0.008929 (E2) **Ref# 213**

DFMEA 95% effective

Occurrence = 0.000446 (M52)

IPG electromechanical failure at implant

Occurrence = 0.008929 (E2) **Ref# 324**

DFMEA 95% effective

Occurrence = 0.000446 (M494)

Labeling includes description of screening procedure, 50% effective, Occurrence = 0.004465 (M356)

Design requirement for torque wrench 99% effective, Occurrence = 0.000089 (M266)

Component damage during procedure:

* Over-tighten then strip set screw
* Damaged lead contact out-of-round

Occurrence = 0.008929 (E2)

**Ref# 215**

**Unintended Revision Surgery**

Occurrence =  4 0.004596

Severity =  3

Risk Index =  12

Therapy not effective

Occurrence = 0.008929 (E2)

**Ref# 320**

Labeling guidance not to bend or kink lead, 50% effective, Occurrence =

0.004465 (M352)

Occurrence = 0.000002

Occurrence = 0.001893

No IPG spare available at implant, Occurrence =

0.008929 (E2) **Ref# 321**

Occurrence = 0.000017

Occurrence = 0.004596

From Part 2

[Occurrence = 0.000025](#_Hlk331142757" \s "4,113328,113350,0,,Occurrence = 0.000000)

Contaminate tunneling sheath by dropping during procedure

Occurrence = 0.008929 (E2)

Design requirement for tunneling tool sheath diameter to be ‘slip fit’ for 3 leads, 100% effective

Occurrence = 0.000000 (M414)

Design requirement for 2 sheaths to be shipped with tunneling tool, 99% effective, Occurrence =

0.000089 (M413)

Multiple leads do not fit in sheath

Occurrence = 1.0 (E0)

Stylet stuck in lead and cannot be removed without damage to lead

Occurrence = 0.008929 (E2)

Design requirement maximum insertion / withdrawal force lead-to-stylet, 99% effective

Occurrence = 0.000089 (M416)

Design requirement to coat stylet with PTFE, 99% effective, Occurrence =

0.000089 (M415)

Occurrence = 0.000000

Body fluid, encapsulation, etc. compromise unused IPG bore, 100% probability

Occurrence = 0.000024

Patient transitions from one lead to 2-lead implant requiring addition of a second lead to existing implanted IPG, Occurrence = 0.000024 (E6)

Design requirement to have bore plug available, 99% effective

Occurrence = 0.000000

M452

## Unintended Revision Surgery - Part 2

Damaged lead due to excessive insertion force

Occurrence = 0.000002

Rep does not have IPG spares

Occurrence =

0.008929 (E2)

‘Malformed existing lead - set screw damage

Occurrence = 0.008929 (E2)

**Ref# 050**

Torque Wrench

Occurrence = 0.000089 (M94)

Labeling guidance to visually inspect for corrosion / damage, 50% effective

Occurrence = 0.004465 (M361)

Clinician tactile feedback, 50% effective

Occurrence = 0.004465 (M360)

Excessive adhesive in IPG header bore

Occurrence = 0.008929 (E2)

**Ref# 020**

DFMEA 95% effective. Note: Process Inspection External Adhesive

Occurrence = 0.000446

(M354)

‘Soft’ lead buckles. Note: 'soft lead' is a mitigation for the nerve damage hazard, and is re-evaluated for hazard on its own here

Occurrence = 0.008929 (E2) **Ref# 017, 217**

Labeling guidance on how to insert lead into IPG w/o buckling, 50% effective

Occurrence = 0.004465 (M363)

Labeling guidance to use sterile water lubricant, 50% effective

Occurrence = 0.004465 (M362)

Clinician tactile feedback, 50% effective

Occurrence = 0.004465 (M360)

Occurrence = 0.000000

Occurrence = 0.000000

Occurrence = 0.000002

Occurrence = 0.000002

Occurrence = 0.000000

To Part 1

bore plug comes loose and detaches from IPG

Occurrence = 0.008929 (E2)

Torque Wrench

99% effective, Occurrence = 0.000089

(M94)

Design requirement to be visible post implant (radiopaque), 50% effective

Occurrence = 0.004465

(M436)

Occurrence = 0.000000

Occurrence = 0.000025

Unattached parts Implanted

Occurrence = 0.000000

From Part 3

[Occurrence = 0.000025](#_Hlk331142757" \s "4,113328,113350,0,,Occurrence = 0.000000)

## Unintended Revision Surgery - Part 3

Unable to insert due to anatomical obstruction

Occurrence = 0.000024

Unable to transition paddle from insertion angle to implant position

Occurrence = 0.002976

Occurrence = 0.000002

To Part 1

Occurrence = 0.000025

Labeling to ensure adequate space, 50% effective

Occurrence = 0.0000119 (M465)

Damage surgical lead by placing in wrong location, Occurrence = 0.000238 (E6)

Lead blank provided for initial positioning, 90% effective

Occurrence = 0.000024

(M464)

Labeling for using elevator to make space, 50% effective

Occurrence = 0.000012 (M466)

Use elevator to help angle transition, 50% effective

Occurrence = 0.001488

(M462)

Use standard surgical tools, 50% effective

Occurrence = 0.001488

(M463)

Device / Lead compatibility DVT testing for insertion force at specified bore and lead size. Testing includes leads that have been exposed to set screw force, 99% effective

Occurrence = 0.000000 (M357)

Unable to insert previously implanted lead in new IPG

Occurrence = 0.000024

Correct IPG model not available at revision

Occurrence = 0.002976

Lead, IPG, extension labeling includes symbol for number of electrodes, 50% effective

Occurrence = 0.001488 (M461)

Model numbers based on number of electrodes, 50% effective

Occurrence = 0.001488 (M460)

Occurrence = 0.000002

Correct IPG or extension model not available at perc lead implant

Occurrence = 0.002976

Lead, IPG, extension labeling includes symbol for number of electrodes, 50% effective

Occurrence = 0.002976 (M461)

Model numbers based on number of electrodes, 50% effective

Occurrence = 0.002976 (M460)

Occurrence = 0.000009

Model 2412 not available for paddle lead implant

Occurrence = 0.002976

Occurrence = 0.000002

Existing implanted lead is incompatible with a new IPG

New lead is incompatible with a new IPG

Occurrence = 0.000014

Unable to place surgical lead or blank in epidural space

Occurrence = 0.000000

Occurrence = 0.005952

# Procedure-Related Risk

## Edema & Seroma

No mitigation

Occurrence = 0.000024

Foreign body response

Occurrence = 0.000024 (E6)

**Ref# 325**

Fluid in pocket

Occurrence = 0.008929 (E2)

**Ref# 163**

No mitigation

Occurrence = 0.008929

**Edema & Seroma**

Occurrence = disclosed, not estimated or controlled

Severity = 1

Occurrence = 0.008953

## Infection of Central Nervous System or Spinal Canal

Methicillin Resistance Staph. Aureus (CSF / Pocket)

Occurrence = 0.000002 (E7)

Unknown cause

**Ref# 184**

Meningitis

Occurrence = 0.000002 (E7)

Unknown cause

**Ref# 185**

**Infection of Central Nervous System or Spinal Canal**

Occurrence = disclosed, not estimated or controlled

Severity = 4

Occurrence = 0.000004

## Infection

Use standard aseptic techniques

Occurrence = 0.000238 (E5)

Non-sterile procedure at implant

Occurrence = 1.00 (E0)

**Ref# 004**

Antibiotic solution in pocket

Occurrence = 0.000238 (E5)

**Infection**

Occurrence = disclosed, not estimated or controlled

Severity = 3

Occurrence = 0.000476

## Trauma

Labeling on tunneling and introducer

Occurrence = 0.000000 (E1)

(M301)

Tunneling procedure

**Ref# 299**

**Trauma**

Occurrence = disclosed, not estimated or controlled

Severity = 3

IPG pocket sizer device

Lead introducer and implant procedure

**Ref# 314**

IPG pocket implant procedure

**Ref# 293**

Delayed surgery

**Ref# 328**

Extended exposure to anesthesia

**Ref# 329**

Excessive bleeding or hemorrhage

No mitigation - Clinician / Clinic related

Warning in labeling to address potential for hematoma

(M364)

No mitigation - Procedure related

Occurrence = 0.000000

Occurrence = 0.000000

Pre-existing condition of patients on anti-coagulants

Occurrence =

**Ref# 330**

General trauma

* Pain
* Implant site tenderness
* Extended healing time

**Ref# 331**

Hypoventilation

**Ref# 338**

## Unintended Revision Surgery

No mitigation

Disease progression, reprogramming cannot compensate for the change

**Ref# 237**

Patient dissatisfaction

**Ref# 286**

No mitigation

**Unintended Revision Surgery**

Occurrence = disclosed, not estimated or controlled

Severity = 3

Labeling guidance on implant procedure

(M365)

Wound dehiscence

**REF # 289**

Occurrence = 0.000000

## Bio-incompatibility

Design requirement for a returned product mailer, 99% effective

Occurrence = 0.000893

(M367)

Standard clinical procedure to sterilize explanted IPGs that are transported, not destroyed, 90% effective

Occurrence = 1.00 (E0)1.00 (E0)1.00 (E0)

Design requirement for smooth outer surfaces on implanted IPGs, minimal areas for bacterial growth, 90% effective

Occurrence = 0.000893

(M138)

**Bio-incompatibility**

Occurrence = disclosed, not estimated or controlled

Severity = 3

Exposure hospital personnel, mail carriers, etc.

Infectious or disease carrying explanted IPG transported

Occurrence = 0.008929 (E2)

**Ref# 331**

Occurrence = 0.000000

Standard clinical procedure to sterilize explanted IPGs that are transported, not destroyed, 90% effective

Occurrence = 0.000893

(M368)

# Risk Estimation Source

A1: RAM error rate used in this report is 2E-12 single event upset (SEU) per bit-hour or 1.46E-9 error per bit-month. Published data ranges from 10−10−10−17 error per bit-hour. Among several references reviewed are: “Single Event Upset at Ground Level”, Eugene Normand, Boeing Defense & Space Group, Seattle, WA 98124-2499, Sept. 3 1998

<http://www.boeing.com/assocproducts/radiationlab/publications/SEU_at_Ground_Level.pdf>

It is acknowledged that failure rates vary widely depending on SRAM, DRAM, Flash, Error Correcting Code (ECC), etc.; however, estimating the error rate is only one step in the process for addressing this scenario. Implementing the associated controls and mitigations is the primary factor in reducing potential for hazard

Error rate = RAM error rate (in error-per-bit-month) \* memory size in bits = 1.46E-9 \* 10k bytes \* 8 bits/byte = 1.46E-9 \* 10240 \* 8 = 0.000120 errors/month

# Revision History

| **Revision**  **Level** | **Revision Description** | **ECN**  **No#** | **Effective**  **Date** |
| --- | --- | --- | --- |
| 1.1 | * Initial Release (Based on risk assessment meetings 1-4) * Formatting Cleanup and minor comments. Spelling, grammar * Updates based on preliminary regulatory plan | 1072 | 07/14/09 |
| 1.2 | * Revise verbiage for consolidation of patient programmer and charger * Add a column for rev 1.2 to table 3 which shows Device or System-Related Risk vs. our releases * Formatting * Insert new hazard rate after E3 = 25 in 100 (new E4, original E4 goes to E5, original E5 to E6, etc.) * Update charge and current density from 20090617 risk meeting. * Updates from device-specific risk review meetings (20090708-20090709) * Updates from risk teleconference meeting 20090722 * Update table of contents (formatted TOC so long titles do not wrap into page numbers) * Used MS Word “document properties” to display document title, number, and revision in headers * Update content to comply with IEC 62304:2006. Note; the sw development process will also need to address this standard in order to meet risk management requirements. * Updates to align with changes to the SCS traceability matrix * Updated from comments in Ben’s 8/6/09 email and items missed from 7/17/09 risk meeting notes * Update from Ben’s 8/5 & 8/6 meeting minutes & notes * split Excess Charge Density or Current Density into two parts, added setscrew mitigations * On DFMEA, I tried not to take double credit by separation (e.g. DFMEA to prevent fluid ingress is indifferent place than DFMEA to prevent IPG failure) * Significant changes to excess charge / current density FTA (resulted in lower risk) * Reorganized use of DFMEA in Under Stimulation Surgical Intervention Required 16.10 to eliminate redundant use * Updated wording in FTA 16.10 Under Stim bottom left #164. Update to trace matrix #164 looks good. * Recalculated Trauma numbers * Changed Heat (16.20) hazard scenarios, major reduction in probability * To clarify changed “Allergic reaction to device/component materials” to “Allergic reaction to biocompatible device/component materials” in allergen exposure fault tree 6.13. * Updated statistics in Unintended Effect FTA 6.47. * Fix trauma FTA numbers 16.43. * Fixed the odd one-liner paragraph in section 6 ... a corrupted bookmark link kept putting it back in even though I removed it several times. * Updated understim non-surgical FTAs 16.1 - 16.5. (deal with ref items 097, 098, 099, & 230) * 16.10 – deleted primary cell failure because a) the system discussed is not primary cell powered and b) all of the scenarios discussed were rechargeable-battery specific. * Recalculated occurrence and over-all cumulated risk. | 1088 | 09/25/09 |
| 1.3 | * Added to review history * Add a column for rev 1.2 to table 3 which shows Device or System-Related Risk vs. our releases * Added tracking numbers to mitigations (Mnnn) * Features and functions analyzed for risk updated to reflect improved understanding in device functionality * Revised wording to say that we believe we are ALARP * Changed “device” or “system” to named parts (e.g. IPG, PPC) where appropriate for improved clarity * Updates from October 2009 risk meetings including Minnetronix FTA notes | 1099 | 11/06/09 |
| 1.4 | * Updated additional controls and causes to fault trees for several hazards * Updated for November 2009 risk meetings * Updated feature definitions * Add design review (management review) to meeting list | 1110 | 01/08/10 |
| 1.5 | * Language cleanup RE pairing, stim off / storage mode * Consolidated duplicates * General revision to mitigations as understand of system operation improved including pairing, safety limits * Minor updates to avoid taking double credit when 2 functional requirements are part of a single mitigation (IPG – PPC interaction during charging) * Fixed conflicting magnet mitigations (magnet only turns IPG off) * Updated language to match QIG terminology | 1152 | 06/03/10 |
| 1.6 | * Clarified wording in several mitigations based on design specification review and tracing activity * Updated lead system risks * Removed marker on contact end for full insertion marker in description of leads * Updated accessory risks   + tunneling tool   + introducer needle   + anchor * Added reference to sources of risk estimation * Added model numbers that are now available | 1166 | 08/06/10 |
| 1.7 | * Mitigation updates based on traceability activity and recent updates to device specifications * Change shelf life requirements to ‘use by date’ for lead and IPG * Added risk scenarios related to bore plug * Added risk scenarios related to 2-piece EPG Extension Cable | 1197 | 11/12/10 |
| 1.8 | * Added model numbers to (Section1) Background, purpose and scope * Added FMEA document numbers to section 2.1 * Updated open item list * Clarified stylet-related mitigations | 1377 | 01/05/12 |
| 1.9 | * Updated description of device functionality for improved accuracy as well as change to magnet functionality, addition of PFT, and PPC pairing PoP or PPC in the field. * Updated Understim Non-Surgical part 6 to reflect magnet on. Included in existing 99% re-activate, no change in occurrence. * Updated Overstim Non-Surgical part 1 to reflect PFT QSO. Included in existing 99% re-activate, no change in occurrence. * Replacement (and implied subsequent re-pairing) effectiveness left at 95% (understim, non-surg part 5) after considering the impact of requiring re-pairing in the field via PPC rather than requiring rep visit. | 1388 | 01/13/12 |
| 1.10 | * Updated hazard severity names for consistency with level of injury * Updated Essential Performance * Removed statement that no SOUP is used in this system * Updated heat to reflect that heat is dependent on both time and temperature * Corrected AND/OR gates & calculations based on review | 1465 | 06/27/12 |
| 1.11 | * Updated toxicity FTA with more specific scenario information * Add risk assessment meeting minutes (20120801 Three Bore IPG and 20120813 Elevator & Lead Blank) and associated risk scenarios * Updated EN ISO 14971 standard to 2012 version * Addressed open items | 1548 | 10/16/12 |
| 1.12 | * Based on IEC 60601-1 safety review   + Updated essential performance   + Added Intended Use   + Added definition of least favorable conditions for each external device to essential function section   + Added expected service life for all non-single use models   + Added sharp edge mitigations M478,M479,M480,M481 * Updated model number list due to project progression * Added new hazard scenarios and mitigations for excessive heat due to lithium battery recharge   + PoP mitigation M469   + PPC mitigation M470   + CP mitigation M471   + EPG mitigation M472 * Removed mitigation M306 from Electrical Shock. * Removed the TETS feature and related mitigations and recalculated risk. * Added MERE 0170 Battery Risk Findings reference document * Added more detail to model number table in scope * Revised M397 to include PoP * Added scenario for incorrect ERI date under misleading information hazard * Added mitigation M407 to address sharp edges on tunneling tool * Revised M398 to IPG design requirement for min 10 Gauss (1 Tesla) field to activate * Updated scope of this document to:   + Remove model 4330 ground pad   + Add models 1081-45T, 1084-45T, 1121-45T, 1124-45T trial leads   + Above changes do not affect content * Combined and generalized EMI-related labeling mitigations   + deleted M15, M16, M18, M274   + modified M13, M17, 166, 400, 391 * Added new mitigations:   + M484: Corrected double entry of mitigation M28, second occurrence of M28 re-identified as M484   + M485: CP Software mitigation to catch 8 vs 12 lead mismatch entry   + M486: Add sonic clean requirement for surgical leads   + M487: Add biocompatibility testing of updated surgical lead processing   + M488: New mitigation and hazard scenario related to disconnected EPG cable   + M489: Elevator tool edge mitigation   + M490: Elevator tool sharp edge inspection |  |  |
| 1.13 | * Added reference to SWFM 0025 IPG software design FMEA * Added missing model numbers to table (1121-45T and 1124-45T) * Updated mitigations for lead guidewire * Added mitigation M303 to EPG electrical shock fault tree * Added reference to 1013760 Endotoxin test report * Removed open item list * Added reference to QARE 0512 Wireless Interface Risk Assessment * Revised M52 from DFMEA in general to Lead System DFMEA   + Added M491 – PoP DFMEA   + Added M492 – PPC DFMEA   + Added M493 – CP DFMEA   + Added M494 – xPG DFMEA   + Added M495 – PFT DFMEA * Changed M7 from PPC DFMEA / Software validation to PPC software validation only * Note: updates completed in caliber * Consolidated or replaced duplicate mitigations   + M57 & M100   + M25 & M318 * Changed M35 from contraindication to warning * Updated text of mitigations M128, M423, M369, M356, M64, M131, M219, M184, M476, M477 * Deleted mitigations M66, M396, M428 * Removed scenario & related mitigations (M437 & M438) for 2-piece trial cable * Added language an references to known anomalies * Removed references to unimplemented CP features (M98, M218, and M270) * Corrected probabilities of understim surgery required to reflect more accurately the probability of “poor contact made at implant” from E2 to a still conservative estimate of E5. | 2117 | 11/27/13 |

1. Revs 1.8 and 1.9 had zero change to any occurrences or risk levels. See revision history for details. [↑](#footnote-ref-1)