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| cid:CID-849d5fd9-dd1b-f791-5650-b15f084064fa  Functional Specification | |
| Title:  24-Channel Implantable Pulse Generator Functional Specification | |
| Document Number and Revision EESP 0071 Rev 1.7 |  |
| Prepared By: | Approved By: |
| Approved By: | Approved By: |

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# Product Description and Intended Use & Scope (F2648)

This device is an Implantable Pulse Generator (IPG) and is designed for use in Spinal Cord Stimulation (SCS).  The IPG is part of a larger system that includes leads and electrodes, an External Pulse Generator (EPG), a Pocket Programmer (PoP), a Patient Programmer / External Charger (PPC), a Clinician Programmer (CP), and various other accessories and tools.  The IPG is an active implantable medical device and shall follow the requirements that apply to the design and testing of such devices.

This document covers electrical and firmware functional requirements. Mechanical requirements are defined in MESP 0113 24 Channel IPG Mechanical Functional Specification and firmware requirements are defined in more detail in SWSP 0112 IPG Software Requirements Specification.

# Definitions (F2649)

| **Acronym or  Term** | **Definition** |
| --- | --- |
| AIMD | Active Implantable Medical Device -  An AMD which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice and which is intended to remain after the procedure. |
| AMD | (Active Medical Device) A medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity. |
| ASK | Amplitude Shift Keying |
| Battery Critical | A battery indication alert that means the battery has been discharged to a very low level and that the IPG is nearing the point of shutting down. |
| Battery Monitor | The mechanism used by the IPG to determine battery capacity. |
| Battery Warning | A battery indication alert that means the battery has been discharged to a low level and needs to be recharged. |
| Channel | An electrical input (sensing) or output (stimulating) on the IPG or EPG. |
| Charging Coil | This is a coil that is connected to the external charger via a cable.  This coil is inductively coupled to the internal charging circuitry for power transfer and diagnostic communications. |
| CHLD | Cumulative Helium Leak Detection - a probabilistic method of determining hermeticity |
| Clinician | The physician, physician assistant, nurse, or other healthcare provider responsible for system implantation and/or follow-up patient monitoring. |
| Clinician Application (CA) | The software application that runs on the Clinician Programmer used to configure the stimulation protocols on the IPG and EPG, and to configure and pair a PP with the IPG/EPG. |
| Clinician Programmer (CP) | A device that the clinician uses to program the IPG or EPG.  This includes both a Clinician Application and Clinician Programmer hardware. |
| Compliance Voltage | The voltage available to drive the desired stimulating current through the electrodes and tissue. |
| Continuous Waveform | A current-controlled delivery of electrical charge to targeted tissue, consisting of alternating phases of stimulation and recovery with no programmable delays. |
| Current Shaping | The ability to change the current amplitude (but not the polarity) during a phase of a pulse, allowing shapes other than current-controlled rectangles. |
| Current Steering | The ability to source and sink current from any combination of channels and allowing each channel’s amplitude to be set independently. |
| Delay | The amount of time between pulses. |
| EAS | Electronic Article Surveillance |
| Electrode | The metal contact on the distal end of a lead; used for stimulating or sensing. |
| ERI | Elective Replacement Interval |
| ESD | Electrostatic Discharge |
| Extension | A connector that provides the electrical connection between the lead and the IPG. |
| External Pulse Generator (EPG) | An AMD nearly identical in function to the IPG, but in an external case.  Also referred to as Trial Stimulator. |
| Implantable Neurostimulator System (INS) | Active implantable medical device intended for electrical stimulation of the central or peripheral nervous system.  NOTE: an implantable neurostimulator can be a single article, or a system consisting of a set of components and accessories which interact to achieve the performance intended by the manufacturer. Not all of these components or accessories might be required to be partially or totally implanted, e.g. programmers, screeners and RF transmitters. |
| IPG | Implantable Pulse Generator:  An active implantable medical device (AIMD) that generates stimulus pulses for therapeutic outcomes. |
| Interphase Delay | The delay between a stimulation phase and the corresponding recovery phase. |
| IPG Port Plug | An accessory used to fill an unused lead bore of the IPG. |
| Lead | A flexible cable with one or more insulated electrical conductors intended to pass current along its length for stimulation or sensing; typically consists of a connector on one end that plugs into an IPG, EPG, or extension cable, and one or more electrodes at the distal end placed on or near the targeted tissue. |
| Lead Anchor | Accessory product used to secure leads to dorsal fascia or supraspinous ligament to prevent movement of the lead following implant |
| LSK | Load Shift Keying |
| Mechanically Intact | During mechanical testing, this refers to the IPG’s ability to maintain hermeticity, to avoid physical separation of any pieces from the device, and to avoid gross deformation that would affect operation or patient safety. |
| MICS | Medical Implant Commuication System (Service) |
| MRI | Magnetic Resonance Imaging |
| Nerve Fiber Recruitment | The ability to selectively activate specific types of nerve fibers in a tissue space by using any combination of current steering, pre-pulses, waveforms, and pulse shaping. |
| Normal Operating Conditions | A set of conditions that define the in vivo environment of the IPG, with all system components connected and providing nominal stimulation. |
| Normal Operation | During electrical and mechanical testing, this refers to the device meeting all specifications without adverse conditions such as component failure, changes in parameter settings, changes in operating mode, loss of memory, false alarms, or unintended operation.   The list of parameters that define unacceptable operation can be found in ISO 14708-3 §27.102 Note 2. |
| Paddle Leads | Leads that contain the electrode in a paddle configuration, typically implanted via a surgical procedure such as a laminectomy or laminotomy. |
| Patient | The person who is receiving the stimulation. |
| PPC | Patient Programmer Charger: A device used by patients both to adjust the stimulation from their IPG or EPG as well as to charge their IPG. |
| Purcutaneous Needle | Needle used to create epidural space access, standard access method for spinal cord stimulation |
| Purcutaneously Implanted Leads: (perc) Leads | Leads implanted via a percutaneous approach, typically via a needle used to access the epidural space. The proximal portion of the lead may be internalized for chronic use or left external for screening purposes. |
| PHA | Preliminary Hazard Analysis |
| PoP | Pocket Programmer external device:  A device used by the patients to activate and provide limited adjustment to the stimulation from their IPG or EPG. |
| Pre-Pulse | One or more minor pulses delivered prior to the stimulus phase, used to polarize the targeted tissue prior to stimulation; when used, this is considered an additional phase of a pulse, in addition to the stimulus phase and recovery phase. |
| Program | A set of pulses, driven at specified rates, intended to treat one or more aspects of a medical condition. |
| Pulse | A current-controlled delivery of electrical charge to targeted tissue using two or more channels and multiple charge-balanced phases. |
| Pulse Shaping | The ability to modify the amplitude of a pulse in such a way that the shape of the current-controlled output can be changed; this allows pulse shapes beyond simple rectangles. |
| Rechargeable Battery | A battery whose charge can be replenished; this battery is “recharged” when the available energy has been consumed. |
| Recovery Phase | The charge-balancing portion of a pulse or continuous waveform. |
| Screening Cable | The screening cable provides a means of connecting the screening lead to the EPG. The screening cable is provided sterile and is intended to connect leads to the EPG during intraoperative and ambulatory screening. |
| Screening Lead | A percutaneous lead intended for temporary use during screening. The connector end of the screening lead is typically connected to a screening cable. |
| SCS | Spinal Cord Stimulation |
| Stimulation Phase | The therapeutic portion of a pulse or continuous waveform. |
| Stylet | Wires utilized to stiffen leads and allow steering of leads when determining placement during implant. |
| Subject | Participant in a clinical trial |
| Surgical Lead | Another term for paddle leads. |
| Swipe | A momentary passing or placement of the magnet across the IPG following by quick removal |
| Therapy | The set of pulses and/or waveforms received by the patient for treatment of a given medical condition. |
| Torque Wrench | Device used to lock leads into the lead bore of an IPG or extension. |
| Transcutaneous Power Transfer | The act of transferring power from an external power source to the implantable device, usually through an inductive link. |
| Tunneling Tool | Accessory used to bury (tunnel) the leads subcutaneously from exit site of the spine to location of IPG placement. |
| UDI | Unique Device Identifier |

# Reference Documents (F2)

## External Documents (F3)

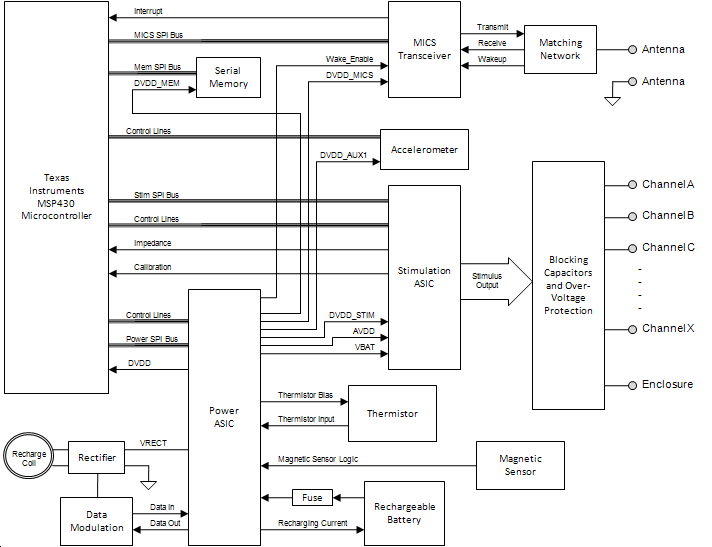
|  |  |
| --- | --- |
| **Document Number** | **Document Name** |
| ANSI C63.4-2003 | Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz |
| ANSI/IEEE c95.1-2005 | IEEE Standard Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz |
| EN 300 330 | Electromagnetic Compatibility and Radio Spectrum, SRD, (Emissions) |
| EN 300 489-3 | Electromagnetic Compatibility and Radio Spectrum, SRD< (Immunity) |
| BS EN 45502-2-1:2003 | Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhthmia (cardiac pacemakers). |
| 47 CFR part 15 (FCC) | Radio Frequency Devices, emissions |
| 47 CFR part 95.628 | MICS transmitter |
| 47 CFR part 95.635 | Unwanted radiation |
| FDA Blue Book Memos – (G95-1) | Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 |
| IEC 60068-2-27:2008 | Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock |
| IEC 60068-2-47:2005 | Environmental testing – Part 2-47: Test - Mounting of specimens for vibration, impact and other similar dynamic tests. |
| IEC 60068-2-64:2008 | Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance |
| IEC 61000-4-3:2010 | Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test |
| ISO 14708-1:2000 | Implants for surgery – Active implantable medical devices |
| ISO 14708-3:2008 | Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators. |
| MIL-STD-750E | Test Method Standard Test Methods for Semiconductor  Devices |
| MIL STD 883E Revision H | Test Method Standard, Microcircuits. |
| RSS-243 | Active Medical Implants Operating in the 402-405 MHz Band (Canadian Standard) |

## Internal Documents (F4)

|  |  |
| --- | --- |
| **Document Number** | **Document Name** |
| MKSP 0069 | 24-Channel Implantable Pulse Generator System Marketing Specification |
| EESP 0074 | Pocket Programmer Functional Specification |
| EESP 0075 | Clinician Programmer Functional Specification |
| MESP 0079 | Filtered Feedthrough Functional Specification |
| MESP 0080 | Model 08xxx, 8 Polar Spinal Cord Lead |
| MESP 0081 | 8 electrode percutaneous lead |
| MESP 0082 | 12 electrode percutaneous lead |
| MKSP 0083 | SCS System Interaction Marketing specification |
| MESP 0084 | 12 Polar Spinal Cord Lead product specification |
| EESP 0085 | Stim ASIC Specifications (External Doc) |
| EESP 0086 | Power ASIC Specifications (External Doc) |
| MESP 0089 | Rechargeable LI-Ion Cell Specification Model 2993 |
| SWSP 0090 | Clinician Programmer Application Software (Functional Spec) |
| MESP 0093 | 24 Channel SCS System General Packaging Specification |
| MESP 0094 | 24 Channel IPG System Labeling Specification |
| SWSP 0112 | IPG Software Requirements Specification |
| MESP 0113 | 24 Channel IPG Mechanical Functional Specification |
| EESP 0097 | Patient Programmer Charger Functional Specification (External Doc) |

# Electrical and Firmware Specifications (F5)

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



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

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

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

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

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

This section of the specification will focus on each of these areas.

## Stimulation Output Specifications (F2688)

The IPG shall have the following channel configurations:

| **ID** | **Title** |
| --- | --- |
| FRS0496 | The IPG shall have a total of 24 detachable output channels. The IPG’s electronics shall support both 3x8 and 2x12 header configurations. |
| FRS0497 | The IPG’s enclosure shall be treated as an additional channel, with the same programmability as the detachable output channels |

### Types of Stimulus Waveforms (F2690)

The IPG shall be capable of producing two types of stimulus waveforms:

| **ID** | **Title** |
| --- | --- |
| FRS0499 | Active Recovery Stimulation, Stimulus Phase    The IPG shall be capable of “active recovery” stimulation, which shall be defined as follows:  cid:CID-543f937d-299c-caeb-f2f0-acc096b1c6cf    Phase Definitions for an "Active Recovery" Pulse Waveform    Current shall be controlled during the stimulus phase of an active recovery waveform. This means that each channel shall be set to source current, set to sink current, or disabled. |
| FRS0500 | Active Recovery Stimulation, Recovery Phase  The IPG shall be capable of “active recovery” stimulation, which shall be defined as follows:  cid:CID-97dfd749-51fb-32c0-1aa2-177d4564ba57    Phase Definitions for an "Active Recovery" Pulse Waveform  Current shall be controlled during the recovery phase of an active recovery waveform. This means that each channel shall be set to source current, set to sink current, or disabled. |
| FRS0502 | Passive Recovery, Stimulus Phase  cid:CID-c5e9ea30-4d1d-d835-6927-ec1d27edc1b1  Phase Definitions for a "Passive Recovery" Pulse Waveform    Current shall be controlled during the stimulus phase of a passive recovery waveform. This means that each channel shall be set to source current, set to sink current, or disabled. |
| FRS0503 | Passive Recovery, Recovery Phase  cid:CID-587efa21-b7bc-d120-8081-ae6f5c6cb26f  Phase Definitions for a "Passive Recovery" Pulse Waveform  Current shall flow passively during the recovery phase of a passive recovery waveform. This means that the charge balance switch shall be closed for every channel. |
| FRS0504 | The IPG shall be capable of generating an independent charge balance correction phase, which shall be defined as a passive charge-balancing phase that can be added to each program in one or more places. The charge balance switch for each channel shall be closed during this phase. |
| FRS0505 | For both types of output waveforms, during the stimulus phase and recovery phase at least one source channel shall be enabled and at least one sink channel shall be enabled. |
| FRS0506 | For both types of output waveforms, during the interphase delay all output channels shall be disabled. No current shall flow between any channels during this delay. |
| FRS0507 | For any active phase in a waveform, the programmed sum of currents being generated by source channels shall be equal to the programmed sum of currents being sunk by sink channels. |
| FRS0508 | The total maximum current that shall be sourced by the IPG during any active phase is 30.0mA. |
| FRS0509 | For both types of output waveforms, the HV supply shall be disabled during the duration of the stimulus phase to minimize noise injection during the pulse. The HV supply shall be enabled during all other phases of the pulse. |
| FRS1213 | For both types of output waveforms, there shall be a delay of at least 40us at the end of the program cycle where no stimulation is active to allow the firmware to synchronize with the stimulation program. |

### Stimulus Output Electrical Specifications (F2691)

The stimulus output shall have the following electrical specifications:

#### Stimulus Phase Electrical Parameters

The stimulus phase shall have the following electrical parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0510 | Stimulus Phase Amplitude Range, Electrode Channels   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | ±0.020 | - | ±15.0 | |
| FRS0511 | Stimulus Phase Amplitude Range, Enclosure Channel   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | ±0.020 | - | ±30.0 | |
| FRS0512 | Stimulus Phase Amplitude Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | uA | -5 | - | -20 | |
| FRS0513 | Stimulus Phase Amplitude Accuracy   |  |  | | --- | --- | | **Range** | **Max** | | Amplitude ≤ 2 mA | ±100 µA | | 2mA < Amplitude < 10 mA | ± (1% + 100µA) | | Amplitude ≥ 10 mA | ±2% | |
| FRS0514 | Stimulus Phase Pulse Width Range   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | 12 | - | 1,500 | |
| FRS0515 | Stimulus Phase Pulse Width Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | 4 | - | |
| FRS0516 | Stimulus Phase Pulse Width Accuracy   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | % | - | - | ±4 | |

#### Interphase Delay Specifications

The interphase delay of a pulse shall have the following parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0517 | Interphase Delay Range   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | 20 | - | 240 | |
| FRS0518 | Interphase Delay Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | 4 | - | |
| FRS0519 | Interphase Delay Accuracy   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | - | ±3 | |

#### Active Recovery Phase Specifications

For an active recovery waveform, the recovery phase shall have the following parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0520 | Active Recovery Phase Amplitude Range, Electrode Channels   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | ±0.020 | - | ±15.0 | |
| FRS0521 | Active Recovery Phase Amplitude Range, Enclosure Channel   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | ±0.020 | - | ±30.0 | |
| FRS0522 | Active Recovery Phase Amplitude Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | uA | -5 | - | -20 | |
| FRS0523 | Active Recovery Phase Amplitude Accuracy   |  |  | | --- | --- | | **Range** | **Max** | | Amplitude ≤ 2 mA | ±100 µA | | 2mA < Amplitude < 10 mA | ± (1% + 100µA) | | Amplitude ≥ 10 mA | ±2% | |
| FRS0524 | Active Recovery Phase Pulse Width Range   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | 12 | - | 7,500 | |
| FRS0525 | Active Recovery Phase Pulse Width Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | 4 | 20 | |
| FRS0526 | Active Recovery Phase Pulse Width Accuracy   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | - | ±5 | |

#### Passive Recovery Phase Specifications

For a passive recovery waveform, the recovery phase shall have the following parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0527 | Passive Recovery Pulse Width Range   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | 12 | - | 9,960 | |
| FRS0528 | Passive Recovery Pulse Width Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | 4 | - | |
| FRS0529 | Passive Recovery Pulse Width Accuracy1   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **PW Range** | **Unit** | **Min** | **Typ** | **Max** | | PW ≤1500 µs | % | - | - | ±4 | | PW > 1500 µs | % | - | - | ±2 | |

#### Charge Balance Correction Phase Specifications

The charge balance correction phase shall have the following parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0530 | Charge Balance Correction Phase Pulse Width Range   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | 0 | - | 9,960 | |
| FRS0531 | Charge Balance Correction Phase Pulse Width Resolution   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | us | - | 4 | - | |
| FRS0532 | Charge Balance Correction Phase Pulse Width Accuracy   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **PW Range** | **Unit** | **Min** | **Typ** | **Max** | | PW ≤1500 µs | % | - | - | ±4 | | PW > 1500 µs | % | - | - | ±2 | |

#### Frequency Specifications

The stimulation output shall have the following frequency parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0533 | Maximum Frequency   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | Hz | 1,930 | 2,000 | 2,070 |   In order to achieve a pulse rate this high, the total sum of the pulse widths and delays in the program must be less than 500 us. If the sum is greater, then the maximum frequency must be determined as follows:                                              Maximum Frequency = 1 / (Sum of Pulse Widths and Delays) |
| FRS0534 | Minimum Frequency   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | Hz | 1.93 | 2.00 | 2.07 | |
| FRS0535 | Frequency Accuracy   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | % | -3.5 | - | +3.5 | |
| FRS0536 | Pulse Jitter (variation in pulse period)   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | % | -0.50 | - | +0.50 | |

#### Leakage Current Specifications

The stimulation output shall have the following leakage current parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0537 | Maximum Net DC Current Per Channel, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | uA | - | - | 1.0 | |
| FRS0538 | Maximum Leakage Current Per Channel, Stimulation Off   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | nA | - | - | 100 | |

#### Output Capacitor Specifications

In order to meet the passive recovery requirements, each output channel on the IPG shall have a series capacitor connected between the current generator(s) and the channel output.  These capacitors shall have the following parameters:

| **ID** | **Title** |
| --- | --- |
| FRS0539 | Series Output Capacitance Required for Electrode Channels   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | uF | 0.80 | 1.00 | 1.20 | |
| FRS0540 | Series Output Capacitance Required for Enclosure Channels   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | uF | 0.80 | 1.00 | 1.20 | |

### Automatic Waveform Adjustment (F4890)

The IPG’s automatic waveform adjustment shall consist of the following elements:

| **ID** | **Title** |
| --- | --- |
| FRS0541 | The IPG shall automatically adjust its output waveform and charge recovery method (passive vs. active) based on the program frequency and the number of pulses in a program. |
| FRS0542 | All pulses in a program shall use the same charge recovery method. If the IPG switches between passive and active as the program frequency is changed, all pulses shall switch to the same recovery method. |

#### Switching between Passive and Active Recovery (F4939)

| **ID** | **Title** |
| --- | --- |
| FRS0543 | For a one-pulse program with a frequency of 175Hz or below, passive recovery waveforms shall be used. For frequencies above 175Hz, active recovery waveforms shall be used. |
| FRS0544 | For a two-pulse program with a frequency of 105Hz or below, passive recovery waveforms shall be used. For frequencies above 105Hz, active recovery waveforms shall be used. |
| FRS0545 | For a three-pulse program with a frequency of 75Hz or below, passive recovery waveforms shall be used. For frequencies above 75Hz, active recovery waveforms shall be used. |
| FRS0546 | For a four-pulse program with a frequency of 60Hz or below, passive recovery waveforms shall be used. For frequencies above 60Hz, active recovery waveforms shall be used. |

#### Default Passive Recovery Waveform (F4891)

For programs running at a frequency at or below the threshold for passive recovery, the following waveforms shall be used:

| **ID** | **Title** |
| --- | --- |
| FRS0548 | For a one-pulse program, the passive recovery waveform shall have the following parameters:  **cid:CID-ee1fc442-74ef-5e34-c64f-afd10481e643**  **Stim Amp:**  Programmable stimulus phase amplitude **Stim PW:**  Programmable stimulus phase pulse width **Interphase Delay:**  Default value “Passive Interphase Delay” **Passive Recovery PW:**  Default value “Passive Recovery Pulse Width” **CBC Phase:**  Default value “Passive Charge Balance Correction Pulse Width” |
| FRS0549 | For a two-pulse program, the passive recovery waveform shall have the following parameters:  cid:CID-2d34e77c-01a7-12f4-a6d2-972db74526ea  **Stim Amp1 and Amp2:**  Programmable stimulus phase amplitudes **Stim PW1 and PW2:**  Programmable stimulus phase pulse widths **Interphase Delay:**  Default value “Passive Interphase Delay” **Passive Recovery PW:**  Default value “Passive Recovery Pulse Width” **CBC Phase:**  Default value “Passive Charge Balance Correction Pulse Width” |
| FRS0550 | or a three-pulse program, the passive recovery waveform shall have the following parameters:  **cid:CID-10a1b5d0-5be1-2173-c422-7416eebed13e**  **Stim Amp1, Amp2, and Amp3:**  Programmable stimulus phase amplitudes **Stim PW1, PW2, and PW3:**  Programmable stimulus phase pulse widths **Interphase Delay:**  Default value “Passive Interphase Delay” **Passive Recovery PW:**  Default value “Passive Recovery Pulse Width” **CBC Phase:**  Default value “Passive Charge Balance Correction Pulse Width” |
| FRS0551 | For a four-pulse program, the passive recovery waveform shall have the following parameters:  **cid:CID-c457f8c4-1497-f002-da94-e61c43d4e082**  **Stim Amp1, Amp2, Amp3, and Amp4:**  Programmable stimulus phase amplitudes **Stim PW1, PW2, PW3, and PW4:**  Programmable stimulus phase pulse widths **Interphase Delay:**  Default value “Passive Interphase Delay” **Passive Recovery PW:**  Default value “Passive Recovery Pulse Width” **CBC Phase:**  Default value “Passive Charge Balance Correction Pulse Width” |

#### Default Active Recovery Waveform (F4940)

For programs running at a frequency above the threshold for active recovery, the following waveforms shall be used:

| **ID** | **Title** |
| --- | --- |
| FRS0552 | For a one-pulse program, the active recovery waveform shall have the following parameters:  cid:CID-dd995474-3a05-64a0-7a56-832fd7827b44  **Stim Amp:**  Programmable stimulus phase amplitude **Stim PW:**  Programmable stimulus phase pulse width **Interphase Delay:**  Default value “Active Interphase Delay” **Active Recovery Amp:** To be calculated **Active Recovery PW:**  To be calculated **CBC Phase:**  Default value “Active Charge Balance Correction Pulse Width” |
| FRS0553 | For a two-pulse program, the active recovery waveform shall have the following parameters:  cid:CID-2b67dbc6-940f-c330-1a36-24375ffdcea8  **Stim Amp1 and Amp2:**  Programmable stimulus phase amplitudes **Stim PW1 and PW2:**  Programmable stimulus phase pulse widths **Interphase Delay:**  Default value “Active Interphase Delay” **Active Recovery Amp:** To be calculated **Active Recovery PW:**  To be calculated **Active Recovery Holdoff:** Default value "Active Recovery Holdoff" **CBC Phase:**  Default value “Active Charge Balance Correction Pulse Width” |
| FRS0554 | For a three-pulse program, the active recovery waveform shall have the following parameters:  cid:CID-c879eed1-44dd-609b-c5af-2a195648b852  **Stim Amp1, Amp2, and Amp3:** Programmable stimulus phase amplitudes **Stim PW1, PW2, and PW3:** Programmable stimulus phase pulse widths **Interphase Delay:** Default value “Active Interphase Delay” **Active Recovery Amp:** To be calculated **Active Recovery PW:** To be calculated **Active Recovery Holdoff:** Default value "Active Recovery Holdoff" **CBC Phase:** Default value “Active Charge Balance Correction Pulse Width” |
| FRS0555 | For a four-pulse program, the active recovery waveform shall have the following parameters:    cid:CID-d2a4f481-a942-31b8-395f-e085a4f8b432  **Stim Amp1, Amp2, Amp3, and Amp4:**  Programmable stimulus phase amplitudes **Stim PW1, PW2, PW3, and PW4:**  Programmable stimulus phase pulse widths **Interphase Delay:**  Default value “Active Interphase Delay” **Active Recovery Amp:** To be calculated **Active Recovery PW:**  To be calculated **Active Recovery Holdoff:**  Default value "Active Recovery Holdoff" **CBC Phase:**  Default value “Active Charge Balance Correction Pulse Width” |

#### Active Recovery Phase Parameter Control Using Recovery Ratio (F2781)

During active recovery, the amplitude and pulse width of the recovery phase shall be controlled as follows:

| **ID** | **Title** |
| --- | --- |
| FRS0556 | The recovery ratio kREC shall be used to calculate the recovery amplitude in the following manner:  AREC = ASTIM / kREC |
| FRS0557 | The recovery ratio shall be used to calculate the recovery pulse width in the following manner:  PWREC = kREC · PWSTIM |
| FRS0558 | The following values for kREC shall be possible:   |  |  |  | | --- | --- | --- | | **kREC** | **Expression** | **Range Limits** | | 5 | AREC = ASTIM / 5 | For ASTIM < 50uA, AREC shall be rounded down to zero | | 4 | AREC = ASTIM / 4 | For ASTIM < 40uA, AREC shall be rounded down to zero | | 3 | AREC = ASTIM / 3 | For ASTIM < 30uA, AREC shall be rounded down to zero | | 2 | AREC = ASTIM / 2 |  | | 1 | AREC = ASTIM |  | |
| FRS0559 | The IPG shall have a default field, “Active Recovery Ratios”, that determine which values of kREC in the table above may be used for the automatic calculation of the recovery ratio. |
| FRS0560 | Because the amplitude selection is limited to 20µA steps, the calculated value for AREC shall be round to the nearest step. This shall add a maximum programmatic (non-hardware) amplitude error of ±10µA for any combination of ASTIM and kREC. |

#### Automatic Calculation of Recovery Ratio (F4941)

In order to calculate the recovery ratio, the IPG shall use the following algorithm:

| **ID** | **Title** |
| --- | --- |
| FRS0561 | The IPG shall determine the period of the program based on the requested frequency, which is defined as follows:  PeriodPROG = 1 / Frequency |
| FRS0562 | If a kREC value of 5 is allowed, the IPG shall determine whether the following formula is true using kREC = 5:  For a one-pulse program:  PeriodPROG ≥ PWSTIM(1 + kREC) + Interphase Delay + CBC+ Sync Delay  For a two-pulse program:  PeriodPROG ≥ (PWSTIM1 + PWSTIM2)(1 + kREC) + 2·(Interphase Delay) + Active Recovery Holdoff+ CBC + Sync Delay  For a three-pulse program:  PeriodPROG ≥ (PWSTIM1 + PWSTIM2 + PWSTIM3)(1 + kREC) + 3·(Interphase Delay)  + 2\*(Active Recovery Holdoff) + CBC + Sync Delay  For a four-pulse program:  PeriodPROG ≥ (PWSTIM1 + PWSTIM2 + PWSTIM3 + PWSTIM4)(1 + kREC) + 4·(Interphase Delay) +3\*(Active Recovery Holdoff)+ CBC + Sync Delay |
| FRS0563 | If the result is not true for kREC = 5 or if kREC = 5 is not allowed, the IPG shall repeat the calculation for kREC = 4 as long as kREC = 4 is allowed. |
| FRS0564 | If the result is not true for kREC = 4 or if kREC = 4 is not allowed, the IPG shall repeat the calculation for kREC = 3 as long as kREC = 3 is allowed. |
| FRS0565 | If the result is not true for kREC = 3 or if kREC = 3 is not allowed, the IPG shall repeat the calculation for kREC = 2 as long as kREC = 2 is allowed. |
| FRS0566 | If the result is not true for kREC = 2 or if kREC = 2 is not allowed, the IPG shall repeat the calculation for kREC = 1 as long as kREC = 1 is allowed. |
| FRS0567 | If the result is not true for kREC = 1 or if kREC = 1 is not allowed, the IPG shall indicate that the requested program frequency is not valid. |

### Frequency Control (F5213)

Control of the output’s frequency shall be handled as follows:

| **ID** | **Title** |
| --- | --- |
| FRS0568 | The IPG shall store a master table of frequencies. |
| FRS0569 | The active program shall run at a frequency that is stored in the master table. |
| FRS0570 | Each program definition shall contain a set of mask bits that determine the valid and invalid frequencies for that program. Each mask bit shall correspond to a location in the master frequency table. |
| FRS0571 | It shall be possible for an external device to change the frequency values in the master frequency table once the IPG is in the field. |
| FRS0572 | It shall be possible for an external device to read the values from the master frequency table. |
| FRS0573 | The master frequency table shall be loaded with the following values during manufacturing:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Location** | **Freq**  **(Hz)** |  | **Location** | **Freq**  **(Hz)** |  | **Location** | **Freq**  **(Hz)** |  | **Location** | **Freq**  **(Hz)** | | 1 | 2 |  | 17 | 35 |  | 33 | 130 |  | 49 | 500 | | 2 | 3 |  | 18 | 40 |  | 34 | 140 |  | 50 | 600 | | 3 | 4 |  | 19 | 45 |  | 35 | 150 |  | 51 | 700 | | 4 | 6 |  | 20 | 50 |  | 36 | 160 |  | 52 | 800 | | 5 | 8 |  | 21 | 55 |  | 37 | 170 |  | 53 | 900 | | 6 | 10 |  | 22 | 60 |  | 38 | 180 |  | 54 | 1000 | | 7 | 12 |  | 23 | 65 |  | 39 | 190 |  | 55 | 1100 | | 8 | 14 |  | 24 | 70 |  | 40 | 200 |  | 56 | 1200 | | 9 | 16 |  | 25 | 75 |  | 41 | 225 |  | 57 | 1300 | | 10 | 18 |  | 26 | 80 |  | 42 | 250 |  | 58 | 1400 | | 11 | 20 |  | 27 | 85 |  | 43 | 275 |  | 59 | 1500 | | 12 | 22 |  | 28 | 90 |  | 44 | 300 |  | 60 | 1600 | | 13 | 24 |  | 29 | 95 |  | 45 | 325 |  | 61 | 1700 | | 14 | 26 |  | 30 | 100 |  | 46 | 350 |  | 62 | 1800 | | 15 | 28 |  | 31 | 110 |  | 47 | 375 |  | 63 | 1900 | | 16 | 30 |  | 32 | 120 |  | 48 | 400 |  | 64 | 2000 | |

### Controlled Source/Sink Configuration (F3115)

The rules for uncontrolled sources and sinks shall be applied as follows:

| **ID** | **Title** |
| --- | --- |
| FRS0574 | For operating modes that apply stimulation to a patient, the IPG shall use only controlled sources and sinks. |
| FRS0575 | During manufacturing testing, the IPG shall be capable of using uncontrolled sources and sinks as needed. |

### Compliance Voltage Calculation (F3119)

The compliance voltage calculation algorithm shall function as follows:

| **ID** | **Title** |
| --- | --- |
| FRS1214 | For the first stimulus phase in the program, the IPG shall determine the following:   1. The term iCHAN shall be the maximum current to be sourced or sunk by an active channel during the stimulus phase. 2. The term iTOTAL shall be the total current being sourced by the IPG during the stimulus phase. 3. The term PWSTIM shall be the pulse width of the stimulus phase. 4. The term SACTIVE shall indicate whether active or passive recovery is being used.  If active, SACTIVE = 1;  if passive, SACTIVE = 0. |
| FRS1215 | The IPG shall have the following constants defined for compliance voltage calculation:   1. The constant CHV shall represent the high-voltage supply's output capacitance. Its default value shall be 9.4µF. 2. The constant VOFFSET shall be one of the terms used to calculate the voltage drop across the sources and/or sinks. Its default value shall be 1.0V. 3. The constant RSOURCE shall be one of the terms used to calculate the voltage drop across the sources and/or sinks. Its default value shall be 100Ω. 4. The constant CCHAN shall represent each channel's blocking capacitor. Its default value shall be 1.0µF. 5. The constant RTARGET shall represent the target load impedance. Its default value shall be 750Ω. |
| FRS0585 | The IPG shall use the following formula to calculate the voltage setting for the high-voltage supply:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | VHV = (1+SACTIVE)· | iTOTAL·PWSTIM | + 2·(VOFFSET + iCHAN·RSOURCE) + 2· | iCHAN·PWSTIM | + iCHAN·RTARGET | | CHV | CCHAN | |
| FRS0586 | The IPG shall calculate the necessary voltage setting for all other pulses in the program, then select the maximum voltage setting. |
| FRS1216 | The IPG shall use the high-voltage lookup table to determine the appropriate setting for the high-voltage supply. This table shall have the following properties:   1. The high-voltage lookup table shall consist of a series of values that correlate a desired voltage to the corresponding setting for the high-voltage supply. 2. The high-voltage lookup table shall be filled in with the calibration data during manufacturing. |
| FRS0589 | If the voltage calculated using the formula for Vhv is less than the minimum voltage in the lookup table, the IPG shall select the minimum value in the table. |
| FRS0590 | If the voltage calculated using the formula for Vhv is greater than the maximum voltage in the lookup table, the IPG shall select the maximum value in the table. |

## Pulse and Program Definition (F2689)

### Program Definition (F3138)

Each program definition shall be configured as shown in the table below:

|  |
| --- |
| **Program Parameters** |
| 1. Program Valid/Invalid  2. Program Enabled/Disabled  3. Program Name  4. Pulse Configurations  5. Valid Program Frequencies  6. Program Frequency Index |

| **ID** | **Title** |
| --- | --- |
| FRS0592 | Program Valid/Invalid shall indicate whether or not the program can be executed by the IPG. If indicated as invalid, the program shall be ignored by the IPG. |
| FRS0593 | Program Enabled/Disabled shall indicate whether the program can be activated by the IPG. The IPG's diagnostic features shall have the ability to disable a program if it detects a fault related to the program. |
| FRS0594 | Program Name shall consist of a string of characters that can be used by an external programmer to display the name of the program. |
| FRS0595 | Pulse Configurations shall consist of one to four pulses that make up the program. Pulses shall be executed in the order in which they are listed. Additional information can be found in the Pulse Definition section. |
| FRS0596 | Valid Program Frequencies shall consist of a set of mask bits that determine the valid frequencies at which the program can run. Each mask bit shall correspond to a location in the master frequency table. |
| FRS0597 | Program Frequency Index shall contain the location in the frequency table that corresponds to the active frequency of the program. |
| FRS0598 | The IPG shall be able to store up to 10 different programs. |
| FRS0599 | Each program definition shall be stored in non-volatile memory. |
| FRS0600 | When running a program, pulses shall be executed consecutively. This means that for programs that have more than one pulse, at the end of the charge recovery phase or holdoff delay of a pulse, the subsequent stimulus phase shall begin immediately. |
| FRS0601 | Each program shall be assigned a single frequency index at any given time. This means that all pulses within a program shall run at the frequency that is stored in the Program Frequency Index. |
| FRS0602 | For programs that have more than one pulse, it shall be possible for the amplitude or pulse width of one of the pulses to be adjusted without affecting the parameters of the other pulse(s). |
| FRS0603 | All program definitions that are used for testing during manufacturing shall be erased from the IPG prior to packaging. |

### Pulse Definition (F2784)

Each pulse definition shall contain waveform parameters that are global to all channels as well as parameters that are specific to each channel. The table below lists the pulse parameters that shall be configurable:

|  |  |
| --- | --- |
| **Global Parameters** | **Channel-Specific Parameters** |
| 1. Pulse Valid/Invalid  2. Pulse Name  3. Stimulus Amplitude Lower Limit  4. Stimulus Amplitude Step Size  5. Amplitude Step Index  6. Pulse Width Lower Limit  7. Pulse Width Upper Limit  8. Pulse Width | 9. Stimulus Amplitude Percentage (x26) |

| **ID** | **Title** |
| --- | --- |
| FRS0605 | Pulse Valid/Invalid shall indicate whether or not the pulse will be executed by the IPG. If indicated as invalid, the pulse shall be ignored by the IPG. |
| FRS0606 | Pulse Name shall consist of a string of characters that can be used by an external programmer to display the name of the pulse. |
| FRS0607 | Stimulus Amplitude Lower Limit shall contain the lowest possible amplitude to which the output can be set. |
| FRS0608 | Stimulus Amplitude Step Size shall contain the amount by which the amplitude will be incremented or decremented when requested by an external programmer. |
| FRS0609 | Amplitude Step Index shall contain the number of steps the amplitude is set above the lower limit. This value, along with the lower limit and the step size, shall be used by the IPG to calculate the default stimulation amplitude. |
| FRS0610 | Pulse Width Lower Limit shall contain the shortest possible duration for the stimulus pulse width. |
| FRS0611 | Pulse Width Upper Limit shall contain the longest possible duration for the stimulus pulse width. |
| FRS0612 | Pulse Width shall contain the active stimulus pulse width. |
| FRS0613 | Stimulus Amplitude Percentage shall contain the percentage of the stimulation amplitude that will be allocated for each channel. |
| FRS0614 | All pulse definitions shall be stored in non-volatile memory. |
| FRS0615 | All pulse definitions that are used for testing during manufacturing shall be erased from the IPG prior to packaging. |

### Pulse Constants (F5214)

The IPG shall use the following constants, applying each one to all pulses:

|  |
| --- |
| **Pulse Constants** |
| 1. Passive Interphase Delay  2. Passive Recovery Pulse Width  3. Passive Charge Balance Correction Pulse Width  4. Active Interphase Delay  5. Active Recovery Ratios  6. Active Charge Balance Correction Pulse Width  7. Stim Phase Pulse Width Step Size  8. Stim Phase Power Supply Disable  9. Increment Lockout Duration  10. Amplitude Steps  11. Frequency Thresholds for Automatic Waveform Adjustment  12. Active Recovery Holdoff |

| **ID** | **Title** |
| --- | --- |
| FRS0617 | Passive Interphase Delay  Passive Interphase Delay defines the delay between the stimulus phase and recovery phase in a passive-recovery waveform. |
| FRS0618 | Passive Recovery Pulse Width  Passive Recovery Pulse Width defines the length of time for the passive recovery phase of each pulse. |
| FRS0619 | Passive Charge Balance Correction Pulse Width  Passive Charge Balance Correction Pulse Width defines the length of time for the CBC phase in each passive-recovery program. |
| FRS0620 | Active Interphase Delay  Active Interphase Delay defines the delay between the Stimulus Phase and Recovery Phase in an active-recovery waveform. |
| FRS0621 | Active Recovery Ratios  Active Recovery Ratios determines the allowed values for kREC that can be used by the IPG’s automatic waveform adjustment algorithm.  The default allowed values for kREC shall be 1, 2, and 4. |
| FRS0622 | Active Charge Balance Correction Pulse Width  Active Charge Balance Correction Pulse Width defines the length of time for the CBC phase in each active-recovery program. |
| FRS0623 | Stim Phase Pulse Width Step Size  Stim Phase Pulse Width Step Size defines the duration by which the pulse width will be incremented or decremented when requested by an external programmer. |
| FRS0624 | Stim Phase Power Supply Disable  Stim Phase Power Supply Disable determines whether the high-voltage boost converter is enabled or disabled during the stimulus phase of a pulse.  By default, the boost converter shall be disabled during the stimulus phase of each pulse. |
| FRS0625 | Increment Lockout Duration  Increment Lockout Duration contains a value that determines the length of time incoming increment commands are ignored.  By default, the increment lockout duration shall be 0.25s. |
| FRS0626 | Amplitude Steps  Amplitude Steps defines the number of available amplitude adjustment steps available.  The default value for this constant shall be 50. |
| FRS0627 | Frequency Thresholds for Automatic Waveform Adjustment  Frequency Thresholds for Automatic Waveform Adjustment define the thresholds at which the IPG switches between passive and active charge recovery.  For a one-pulse program, the default frequency threshold shall be 175Hz.  For a two-pulse program, the default frequency threshold shall be 105Hz.  For a three-pulse program, the default frequency threshold shall be 75Hz.  For a four-pulse program, the default frequency threshold shall be 60Hz. |
| FRS1217 | Active Recovery Holdoff  Active Recovery Holdoff defines the delay from the end of the active charge recovery phase to the start of the next pulse. |
| FRS0628 | The IPG shall be programmed with these constants prior to packaging. |
| FRS0629 | The IPG shall have the ability to change the value for each constant listed in this requirement via commands from an external programmer. |
| FRS0630 | All constants shall be stored in non-volatile memory. |

## Adjustment of Stimulation Output (F2697)

### Beginning a Program (F2870)

When the IPG receives a command to begin running a program, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0631 | The IPG shall verify that the requested program is valid and enabled prior to starting it. Whether the program is valid is determined by the Program Valid/Invalid field in the program definition. Whether the program is enabled is determined by the Program Enabled/Disabled field in the program definition. |
| FRS0632 | The IPG shall perform a pre-stimulation data integrity check to verify that all data associated with the requested program is valid. |
| FRS0633 | The IPG shall use the most-recently used stimulation parameters for the requested program. |
| FRS0634 | The IPG shall verify that the stimulation parameters for the requested program do not exceed the Current Density or Charge Density Limits. |
| FRS0635 | The IPG shall verify that the battery level is above the Battery Critical Level. |
| FRS0636 | The IPG shall verify that the pulse guard is working correctly. |
| FRS0637 | The IPG shall calculate the appropriate compliance voltage setting and enable the stimulation hardware. |
| FRS0639 | The IPG shall verify that all data has been properly written to the stimulation hardware. |
| FRS0640 | The IPG shall start the program run-time counter. |
| FRS0641 | The IPG shall perform a ramping up of the stimulation current. |
| FRS0642 | The IPG shall verify the stimulation program period with the stimulation turned on. |

#### Pre-Stimulation Data Integrity Check (F5818)

The data integrity check prior to the start of a program shall verify these areas of memory:

| **ID** | **Title** |
| --- | --- |
| FRS0643 | Program definition. |
| FRS0644 | Most-recently used settings for the program, including pulse amplitudes, pulse widths, and program frequency. |
| FRS0645 | Pulse constants. |
| FRS0646 | Stimulation safety limits. |
| FRS0647 | The master frequency table. |
| FRS0648 | Stimulation calibration tables. |

#### Stimulation Output Check (F3166)

[reserved]

#### Ramping (F3167)

Ramping shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0657 | The Ramp Duration constant shall be applied to all programs. Possible values for the Ramp Duration shall be 0s (ramp disabled) to 8s in 1s increments. The default value for the ramp time shall be 2s. |
| FRS0658 | If ramping is enabled, the ramp shall have at least one step. |
| FRS0659 | If ramping is disabled, the IPG shall jump directly from no output to full-amplitude output. |
| FRS0660 | The ramp profile shall proceed from zero current to full-amplitude current in a linear fashion. |
| FRS0661 | While ramping, the IPG shall not allow stimulation parameters to be updated. This includes changes to the amplitude, pulse width, or program frequency. |
| FRS0662 | While ramping, if the IPG receives a command to stop stimulation, all stimulation shall be stopped immediately. |

### Ending a Program (F2871)

When the IPG receives a command to stop running a program, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0663 | The IPG shall stop stimulation immediately after it reaches the end of the program cycle that is running. |
| FRS0664 | The IPG shall disable all stimulation hardware. |
| FRS0665 | The IPG shall stop the counter for program run-time. |
| FRS0666 | The IPG shall save the program's stimulation settings so that these can be used the next time the program is initiated. |
| FRS0667 | The IPG shall perform a background impedance check if background impedance checks are enabled. |

### Increasing Amplitude (F2872)

When the IPG receives a command to increment the amplitude of a pulse, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0669 | If the command applies to a single pulse in the program, the IPG shall determine whether an amplitude increase is allowed based on the Amplitude Step Index in the pulse definition. If an increase is not allowed, the IPG shall report this to the external programming device and the command shall be ignored. |
| FRS0670 | If the command applies to all pulses in the program, the IPG shall determine for which pulses an amplitude increase is allowed based on the Amplitude Step Indexes in each pulse definition. If none of the pulses are allowed to be increased, the IPG shall report this to the external programming device. Pulses for which an increase is allowed shall continue to the calculation step. |
| FRS0671 | The IPG shall calculate the amplitude increases for all channels in each pulse that is to be incremented. |
| FRS0672 | The IPG shall verify that the calculated amplitude for each channel is below that channel's Current Density Limit. |
| FRS0673 | The IPG shall verify that the calculated charge for each channel (amplitude times pulse width) is below that channel's Charge Density Limit. |
| FRS0674 | If the amplitude increase for any channel causes the Current Density Limit or Charge Density Limit to be exceeded, the IPG shall report an error to the external programming device and shall not increment the amplitude. |
| FRS0675 | The IPG shall calculate the compliance voltage based on the new amplitude parameters and adjust the high-voltage power supply if necessary. |
| FRS0676 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Decreasing Amplitude (F5845)

When the IPG receives a command to decrement the amplitude of a pulse, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0677 | If the command applies to a single pulse in the program, the IPG shall determine whether an amplitude decrease is allowed based on the Amplitude Step Index in the pulse definition. If a decrease is not allowed, the IPG shall report this to the external programming device and the command shall be ignored. |
| FRS0678 | If the command applies to all pulses in the program, the IPG shall determine for which pulses an amplitude decrease is allowed based on the Amplitude Step Indexes in each pulse definition. If none of the pulses are allowed to be decreased, the IPG shall report this to the external programming device. Pulses for which a decrease is allowed shall continue to the calculation step. |
| FRS0679 | The IPG shall calculate the amplitude decreases for all channels in each pulse that is to be decremented. |
| FRS0680 | The IPG shall calculate the compliance voltage based on the new amplitude parameters and adjust the high-voltage power supply if necessary. |
| FRS0681 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Increasing Pulse Width (F5846)

When the IPG receives a command to increment the pulse width of a pulse, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0682 | The IPG shall determine whether a pulse width increase is allowed based on the Pulse Width Upper Limit in the pulse definition. If an increase is not allowed, the IPG shall report this to the external programming device and the command shall be ignored. |
| FRS0683 | The IPG shall determine the new pulse width based on the Pulse Width Step Size defined in the Pulse Constants. |
| FRS0684 | The IPG shall verify that the calculated charge for each channel (pulse width times amplitude) is below that channel's Charge Density Limit. |
| FRS0685 | If the pulse width increase causes the Charge Density limit to be exceeded, the IPG shall report an error to the external programming device and shall not increment the pulse width. |
| FRS0686 | The IPG shall calculate the compliance voltage based on the new pulse width parameters and adjust the high-voltage power supply if necessary. |
| FRS0687 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Decreasing Pulse Width (F2873)

When the IPG receives a command to decrement the pulse width of a pulse, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0688 | The IPG shall determine whether a pulse width decrease is allowed based on the Pulse Width Lower Limit in the pulse definition. If a decrease is not allowed, the IPG shall report this to the external programming device and the command shall be ignored. |
| FRS0689 | The IPG shall determine the new pulse width based on the Pulse Width Step Size defined in the Pulse Constants. |
| FRS0690 | The IPG shall calculate the compliance voltage based on the new pulse width parameters and adjust the high-voltage power supply if necessary. |
| FRS0691 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Increasing Frequency (F2874)

When the IPG receives a command to increment the frequency of a program, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0692 | The IPG shall determine the new frequency based on the Valid Program Frequencies field in the program definition. |
| FRS0693 | The IPG shall use the Automatic Waveform Adjustment Algorithm to determine the type of recovery waveform to be used. If the waveform needs to change, the IPG shall update the pulses accordingly. |
| FRS0694 | If the Automatic Waveform Adjustment Algorithm determines that the period is too short to run the program or if it finds no valid frequencies above the current frequency, the IPG shall notify the external programmer and the frequency shall not be incremented. |
| FRS0695 | The IPG shall calculate the compliance voltage based on the new waveform parameters and adjust the high-voltage power supply if necessary. |
| FRS0696 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Decreasing Frequency (F2875)

When the IPG receives a command to decrement the frequency of a program, it shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0697 | The IPG shall determine the new frequency based on the Valid Program Frequencies field in the program definition. |
| FRS0698 | The IPG shall use the Automatic Waveform Adjustment Algorithm to determine the type of recovery waveform to be used. If the waveform needs to change, the IPG shall update the pulses accordingly. |
| FRS0699 | If the IPG has no valid frequencies below the current frequency, it shall notify the external programmer and the frequency shall not be decremented. |
| FRS0700 | The IPG shall calculate the compliance voltage based on the new waveform parameters and adjust the high-voltage power supply if necessary. |
| FRS0701 | The IPG shall update all stimulation parameters, verify that they were correctly written to the stimulation hardware, then switch to the new parameters without ramping. |

### Increment Rate Lockout (F5834)

The IPG shall have an increment-rate lockout feature that dictates the rate at which stimulation parameters (amplitude, pulse width or frequency) can be incremented by the user.  This feature shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0702 | The lockout shall consist of a duration between 0s (lockout disabled) to 2s. The duration shall be programmable to a resolution of 1ms. |
| FRS0703 | The lockout shall be initiated when an increment command is completed. |
| FRS0704 | The IPG shall return an error code in response to any incoming increment commands for the duration of the lockout. |
| FRS0705 | The lockout feature shall apply globally across all pulses and programs. |

## Stimulation Safety Mechanisms (F2698)

### Pulse Guard (F2856)

The IPG shall have a pulse guard that stops stimulation in the event that the stimulation clock source goes into a fault state while generating a stimulation pulse.  The pulse guard shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0706 | The pulse guard shall use a timing mechanism that is completely independent of the stimulation timing source. This means that the pulse guard shall continue to perform as required if the stimulation timing source fails. |
| FRS0707 | The pulse guard shall be initiated at the beginning of each stimulus phase in a program. If active charge recovery is being used, the pulse guard shall also be initiated at the beginning of each active recovery phase in the program. |
| FRS0708 | The pulse guard shall be programmed for each phase so that it triggers when the pulse width exceeds 250us more than the value programmed. |
| FRS0709 | If the pulse guard is tripped, it shall immediately stop all stimulation by disabling the IPG's stimulation hardware. |
| FRS0710 | If the pulse guard is tripped, it shall generate an internal fault condition. |

### Current Density Limit (F2858)

The IPG shall have a current density limit feature with the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0711 | Each channel in the IPG shall have a separate current density limit defined. |
| FRS0712 | No current amplitude used for a channel during stimulation shall be allowed to exceed the current density limit. |
| FRS0713 | The current density limit values in the IPG shall be capable of being set via command from an external programming device. These values shall be stored in non-volatile memory. |

### Charge Density Limit (F2859)

The IPG shall have a charge density limit feature with the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0714 | Each channel in the IPG shall have a separate charge density limit defined. |
| FRS0715 | No combination of amplitude and pulse width (total charge) per phase shall be allowed to exceed the charge density limit. |
| FRS0716 | The charge density limit values in the IPG shall be capable of being set via command from an external programming device. These values shall be stored in non-volatile memory. |

### Internal Watchdog (F2862)

The IPG’s microcontroller shall use an internal watchdog to reset the system in the event of abnormal program execution during stimulation.  This feature shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0717 | When a reset occurs due to the internal watchdog, stimulation shall be stopped in a safe manner (i.e., not relying on the pulse guard to stop stimulation). |
| FRS0718 | When a reset occurs, stimulation shall not be restarted automatically by the IPG after coming out of the reset. A command from one of the external programming devices shall be required to restart stimulation. |
| FRS0719 | An error event shall be logged indicating that an unintended reset has occurred. |

### Brownout Detection Circuitry (F8541)

[RESERVED]

## Test and Titration Stimulation (F8499)

Test stimulation provides a means to generate pulses that cannot be generated using normal patient programs and safety rules.  Test stimulation is only intended to be used for manufacturing testing and has a special command set that will not be compatible with the external devices normally used to program and control the IPG.

Titration stimulation provides a means to support the programming of the IPG.  Titration stimulation allows quick updates via the clinician programmer using special commands.

Test stimulation and titration stimulation are similar in that they are special modes for generating pulses.  These modes operate differently than normal patient stimulation in that updates can occur much faster, giving the external device more control over the IPG’s output.

### Test Stimulation Definition (F8500)

Test stimulation shall be defined as follows:

#### Test Stimulation Parameters

Test stimulation shall be configured as shown in the table below:

|  |
| --- |
| **Test Stimulation Parameters** |
| 1. Compliance Voltage Value  2. Frequency Index  3. Number of Test Pulses |

| **ID** | **Title** |
| --- | --- |
| FRS0723 | Compliance Voltage Value shall contain the value of the high-voltage supply to be used during test stimulation. |
| FRS0724 | Frequency Index shall contain the location of the test stimulation frequency in the Master Frequency Table. |
| FRS0725 | Number of Test Pulses shall contain the number of pulses in the test stimulation program cycle. Test stimulation shall be capable of driving zero to four test pulses. The test pulses shall be executed in the order in which they are programmed. |

#### Test Pulse Parameters

The parameters for each test pulse shall be configured as shown in the table below:

| **Test Pulse Parameters** |
| --- |
| 1.  Test Pulse Amplitude  2.  Channel Amplitude Percentages (x26)  3.  Stimulus Phase Pulse Width  4.  Interphase Delay  5.  Recovery Ratio  6.  Passive Recovery Pulse Width  7.  CBC Pulse Width |

| **ID** | **Title** |
| --- | --- |
| FRS0727 | Test Pulse Amplitude  Test Pulse Amplitude shall contain the total current to be sourced during the stimulus phase of the test pulse. |
| FRS0728 | Channel Amplitude Percentages (x26)  Channel Amplitude Percentages shall define the current to be sourced or sunk by each channel during the stimulus phase of the pulse.  In this field, it shall be possible to program one or more channels to be uncontrolled sinks along with one or more controlled sources.  It shall also be possible to program one or more channels to be uncontrolled sources along with one or more controlled sinks.  The IPG shall indicate that the test pulse is invalid if both uncontrolled sources and uncontrolled sinks are configured for the set of channel amplitudes. |
| FRS0729 | Stimulus Phase Pulse Width  Stimulus Phase Pulse Width shall define the pulse width of the stimulus phase of the test pulse. |
| FRS0730 | Interphase Delay  Interphase Delay shall define the delay between the end of the test pulse’s stimulus phase and the start of the recovery phase. |
| FRS0731 | Recovery Ratio  Recovery Ratio shall define the value of kREC that is used to calculate the active recovery amplitude and pulse width.  If the Recovery Ratio field is programmed with a kREC value of 1, 2, 3, 4, or 5 the test pulse shall use active recovery.  If the Recovery Ratio field is programmed with a kREC value of zero, the test pulse shall use passive recovery. |
| FRS0732 | Passive Recovery Pulse Width  Passive Recovery Pulse Width shall define the pulse width of the passive recovery phase.  The passive recovery shall only be active if the Recovery Ratio is programmed to a value of zero. |
| FRS0733 | CBC Pulse Width  CBC Pulse Width shall define the pulse width of the charge balance correction phase. |

### Titration Stimulation Definition (F8501)

Titration stimulation shall be configured as shown in the table below:

|  |
| --- |
| **Titration Stimulation Parameters** |
| 1. Frequency Index  2. Number of Titration Pulses |

The parameters for each titration pulse shall be configured as shown in the table below:

| **Titration Pulse Parameters** |
| --- |
| 1.  Titration Pulse Amplitude  2.  Channel Amplitude Percentages (x26)  3.  Stimulus Phase Pulse Width |

| **ID** | **Title** |
| --- | --- |
| FRS0734 | Frequency Index  Frequency Index shall contain the location of the titration stimulation frequency in the Master Frequency Table. |
| FRS0735 | Number of Titration Pulses  Number of Titration Pulses shall contain the number of pulses in the titration stimulation program cycle.  Titration stimulation shall be capable of driving zero to four titration pulses.  The titration pulses shall be executed in the order in which they are programmed. |
| FRS0736 | Titration Pulse Amplitude  Titration Pulse Amplitude shall contain the total current to be sourced during the stimulus phase of the titration pulse. |
| FRS0737 | Channel Amplitude Percentages (x26)  Channel Amplitude Percentages shall define the current to be sourced or sunk by each channel during the stimulus phase of the pulse.  The IPG shall only use controlled sources and sinks during titration stimulation. |
| FRS0738 | Stimulus Phase Pulse Width  Stimulus Phase Pulse Width shall define the pulse width of the stimulus phase of the titration pulse. |
| FRS0743 | FRS0743: For all other titration stimulation parameters (passive interphase delay, passive recovery pulse width, passive CBC pulse width, active interphase delay, active recovery ratios, active recover holdoff and active CBC pulse width), the IPG shall use the same values used during normal patient stimulation as defined in Pulse Constants. - Doc\_IPA Functional Specification |
| FRS0744 | The IPG shall use the automatic waveform adjustment algorithm to determine whether active or passive recovery is used during titration stimulation. |
| FRS0745 | The IPG shall automatically calculate the compliance voltage during titration stimulation. |

### Control of Test and Titration Stimulation (F8503)

Test and titration stimulation shall be controlled as follows:

| **ID** | **Title** |
| --- | --- |
| FRS0746 | Test stimulation or titration stimulation shall only be capable of being enabled while the IPG is in Idle or Recharge mode. If the IPG is in Storage, Bootloader, or Stimulation mode, the IPG shall not enable test or titration stimulation. |
| FRS0747 | The IPG shall be capable of enabling test or titration mode without providing stimulation output. This means that the IPG shall be capable of enabling the internal stimulation hardware when test or titration mode is enabled. |
| FRS0748 | The start of a test or titration program shall be executed as follows: 1  1.    The IPG shall verify that the battery level is acceptable for stimulation. |
| FRS0749 | The start of a test or titration program shall be executed as follows: 2  2.  The IPG shall verify that the stimulation parameters included in the test or titration program do not exceed the Current Density and Charge Density limits. If any limits are exceeded, the test or titration program shall not be started. |
| FRS0750 | The start of a test or titration program shall be executed as follows: 3  3.  The IPG shall write the stimulation parameters to the stimulation hardware then verify that the parameters were written correctly. |
| FRS0751 | The start of a test or titration program shall be executed as follows: 4  4.  If the IPG is actively running another test or titration program, it shall wait until the stimulation cycle is complete then immediately switch to the new program without ramping |
| FRS0752 | The start of a test or titration program shall be executed as follows: 5  5.  If the IPG is not actively running another test or titration program, it shall start the new program immediately without ramping. |
| FRS0754 | The stopping of test or titration stimulation shall be executed as follows: 1  The IPG shall wait until the current stimulation cycle is complete, then stop the test or titration program. |
| FRS0755 | The stopping of test or titration stimulation shall be executed as follows 2:  2.  The IPG shall keep the stimulation hardware active unless a command is received to disable test or titration mode. |
| FRS0756 | Test or titration mode shall be disabled if any of the following conditions are true:  1. Test or titration mode shall be disabled if the battery monitor detects that the battery has dropped too low to continue stimulation. |
| FRS0757 | Test or titration mode shall be disabled if any of the following conditions are true:2  2. Test or titration mode shall be disabled if the MICS session with the clinician programmer is lost. |
| FRS0758 | Test or titration mode shall be disabled if any of the following conditions are true:3  3. Test or titration mode shall be disabled if the IPG receives a command from any external programmer to stop stimulation. |
| FRS0760 | When actively running a test or titration program, the IPG shall not respond to commands intended for normal patient stimulation. |

## Operating Modes (F2699)

### Storage Mode (F2850)

**Description:**  Storage Mode is the lowest-power state of the IPG.  In this mode, almost all active circuitry will be disconnected from the battery and all internal power supplies will be off.

The following specifications shall apply to Storage Mode:

| **ID** | **Title** |
| --- | --- |
| FRS0761 | While in Storage Mode, the IPG shall not be capable of concurrently operating in any other modes. |
| FRS0762 | The IPG shall enter Storage Mode if it receives a command over the MICS link to enter Storage Mode. |
| FRS0763 | The IPG shall enter Storage Mode if the battery monitor circuit detects that the battery has reached its cutoff voltage. |
| FRS0764 | The IPG shall enter Storage Mode if the magnet sensor has detected the presence of an external magnet for 5s +/- 2s or longer. |
| FRS0765 | The only event that shall cause the IPG to exit Storage Mode is the engagement of the inductive link. |
| FRS0766 | MICS Communications shall be disabled while the IPG is in Storage Mode: |
| FRS0767 | Stimulation shall be disabled while the IPG is in Storage Mode. |
| FRS0768 | Battery Monitor shall be disabled while the IPG is in Storage Mode. |
| FRS0769 | The Magnet Sensor shall be disabled while the IPG is in Storage Mode. |
| FRS0770 | Temperature Measurement shall be disabled while the IPG is in Storage Mode. |
| FRS0771 | The Charge Controller shall be disabled while the IPG is in Storage Mode. |
| FRS0773 | All diagnostics shall be disabled while the IPG is in Storage Mode. |
| FRS0774 | The IPG shall be put into Storage Mode prior to leaving the factory. |

### Idle Mode (F2851)

**Description:**  Idle Mode is a low-power state of the IPG where it is powered up but is not stimulating, recharging, or running the bootloader.  In this mode, the IPG will respond to MICS commands and can run basic background functions and diagnostics.

The following specifications shall apply to Idle Mode:

| **ID** | **Title** |
| --- | --- |
| FRS0775 | While in Idle Mode, the IPG shall not be capable of concurrently operating in any other modes. |
| FRS0776 | While in Stimulation Mode only, the IPG shall enter Idle Mode if it receives a command over the MICS link to stop a stimulation program. |
| FRS0777 | While in Stimulation Mode only, the IPG shall enter Idle Mode if the battery monitor detects that the battery has reached its minimum voltage for safe stimulation. |
| FRS0778 | While in Stimulation Mode only, the IPG shall enter Idle Mode if the magnet sensor detects a magnet swipe. |
| FRS0779 | While in Stimulation Mode only, the IPG shall enter Idle Mode if it detects a fault that requires stimulation to be stopped. |
| FRS0780 | While in Recharge Mode only, the IPG shall enter Idle Mode if the inductive link becomes disengaged. |
| FRS0781 | While in Bootloader Mode, the IPG shall enter Idle Mode once it completes the load process. |
| FRS0782 | The IPG shall exit Idle Mode if it receives a command to turn on stimulation, causing a transition to Stimulation Mode. |
| FRS0783 | The IPG shall exit Idle Mode if the inductive link becomes engaged, causing a transition to Recharge Mode. |
| FRS0784 | The IPG shall exit Idle Mode if the magnet sensor detects the presence of an external magnet for 5s or longer, causing a transition to Storage Mode. |
| FRS0785 | The IPG shall exit Idle Mode if it receives a command to enter Storage Mode. |
| FRS0786 | The IPG shall exit Idle Mode if the battery monitor detects that the battery has reached its cutoff voltage, causing a transition to Storage Mode. |
| FRS0787 | MICS Communications shall be enabled while the IPG is in Idle Mode. |
| FRS0788 | The Battery Monitor shall be enabled while the IPG is in Idle Mode. |
| FRS0789 | The Magnet Sensor shall be enabled while the IPG is in Idle Mode. |
| FRS0791 | Stimulation shall be disabled while the IPG is in Idle Mode. |
| FRS0792 | Temperature Measurement shall be disabled while the IPG is in Idle Mode. |
| FRS0793 | The Charge Controller shall be disabled while the IPG is in Idle Mode. |

### Stimulation Mode (F2853)

**Description:**  Stimulation Mode is a high-power state of the IPG where it is actively stimulating.  In this mode, the IPG will respond to MICS commands and will run advanced background functions and diagnostics.

The following specifications shall apply to Stimulation Mode:

| **ID** | **Title** |
| --- | --- |
| FRS0799 | While in Stimulation Mode, the IPG shall be capable of concurrently operating in Recharge mode. |
| FRS0800 | While in Idle Mode or Recharge Mode, the IPG shall enter Stimulation Mode if it receives a command over the MICS link to start a stimulation program. |
| FRS1219 | While in Idle Mode or Recharge Mode, the IPG shall enter Stimulation Mode if the magnet sensor detects a magnet swipe. |
| FRS0801 | The IPG shall exit Stimulation Mode if it receives a command to turn off stimulation, causing a transition to Idle Mode or Recharge Mode. |
| FRS0802 | The IPG shall exit Stimulation Mode if the magnet sensor detects the presence of a magnet swipe, causing a transition to Idle Mode or Recharge Mode. |
| FRS0803 | The IPG shall exit Stimulation Mode if it receives a command to enter Storage Mode. |
| FRS0804 | The IPG shall exit Stimulation Mode if the battery monitordetects that the battery has reached its minimum voltage for safe stimulation, causing a transition to Idle Mode or Recharge Mode. |
| FRS0805 | The IPG shall exit Stimulation Mode if it detects a fault that requires stimulation to be stopped, causing a transition to Idle Mode or Recharge Mode. |
| FRS0806 | MICS Communications shall be enabled while the IPG is in Stimulation Mode. |
| FRS0807 | Stimulation shall be enabled while the IPG is in Stimulation Mode. |
| FRS0808 | The Battery Monitor shall be enabled while the IPG is in Stimulation Mode. |
| FRS0809 | The Magnet Sensor shall be enabled while the IPG is in Stimulation Mode. |
| FRS0811 | Temperature Measurement shall be disabled while the IPG is in Stimulation Mode, unless the IPG also happens to be running in Recharge Mode. |
| FRS0812 | The Charge Controller function shall be disabled while the IPG is in Stimulation Mode, unless the IPG also happens to be running in Recharge Mode. |

### Recharge Mode (F5925)

**Description:**  Recharge Mode is a high-power state of the IPG where it is actively recharging the battery.  In this mode, the IPG will respond to MICS commands and will run advanced background functions and diagnostics.

The following specifications shall apply to Recharge Mode:

| **ID** | **Title** |
| --- | --- |
| FRS0819 | While in Recharge Mode, the IPG shall be capable of concurrently operating in Stimulation mode. |
| FRS0820 | The only event that shall cause the IPG to enter Recharge Mode is when the inductive link becomes engaged while the IPG is in Storage Mode, Idle Mode, or Stimulation Mode. |
| FRS0821 | The following events shall cause the IPG to exit Recharge Mode is when causing a transition to Idle Mode, or Stimulation Mode.  The inductive link becomes disengaged |
| FRS1220 | The following events shall cause the IPG to exit Recharge Mode causing a transition to Idle Mode, or Stimulation Mode.  A charging error occurs |
| FRS1221 | The following events shall cause the IPG to exit Recharge Mode is when causing a transition to Idle Mode, or Stimulation Mode.  The IPG's temperature exceeds the maximum allowed limit |
| FRS1222 | The following events shall cause the IPG to exit Recharge Mode is when causing a transition to Idle Mode, or Stimulation Mode.  Charging is completed |
| FRS0822 | MICS Communications shall be enabled while the IPG is in Recharge Mode. |
| FRS0823 | The Battery Monitor shall be enabled while the IPG is in Recharge Mode. |
| FRS0824 | The Magnet Sensor shall be enabled while the IPG is in Recharge Mode. |
| FRS0825 | Temperature Measurement shall be enabled while the IPG is in Recharge Mode. |
| FRS0826 | The Charge Controller shall be enabled while the IPG is in Recharge Mode. |

### Bootloader Mode (F8518)

**Description:**  Bootloader Mode is a high-power state of the IPG where it is actively saving firmware or calibration data.  In this mode, the IPG will respond to certain MICS commands and only Recharge Mode is allowed to run concurrently.

The following specifications shall apply to enter or exit Bootloader Mode:

| **ID** | **Title** |
| --- | --- |
| FRS0834 | While in Idle Mode or Recharge Mode, the IPG shall enter Bootloader Mode if it receives a command over the MICS link to enter Bootloader Mode. |
| FRS0835 | The IPG shall enter Bootloader Mode if it detects a fault that requires Bootloader Mode to be corrected. |
| FRS0836 | The IPG shall exit Bootloader Mode following the completion of the load process, causing a transition to Idle Mode or Recharge Mode. |
| FRS0837 | The IPG shall exit Bootloader Mode if the magnet sensor detects the presence of an external magnet for 5s or longer, causing a transition to Storage Mode. |
| FRS0838 | MICS Communications shall be enabled while the IPG is in Bootloader Mode. |
| FRS1307 | The Magnet Sensor shall be enabled while the IPG is in Bootloader Mode: |

### External Magnet Effect on Operating Modes (F5926)

The IPG shall have a sensor that can detect the presence of an external magnet.  This sensor shall behave in the following manner:

| **ID** | **Title** |
| --- | --- |
| FRS0846 | By default, if stimulation is active, the IPG shall turn off stimulation if the magnet sensor detects magnet swipe. If stimulation is inactive, the IPG shall turn on stimulation if the magnet sensor detects a magnet swipe. This feature shall be capable of being disabled or enabled by a command from an external programmer. |
| FRS0847 | The IPG shall transition to Storage Mode if the magnet sensor detects the presence of an external magnet for 5s +/- 2s or longer. |
| FRS1223 | A magnet swipe shall be defined as an activation of the IPG's magnet sensor via placement of an external magnet on or near the patient's skin, followed by the removal of the magnet within a certain time window. Alternating magnetic fields detected by the sensor shall not be interpreted as swipes. |

## Internal Power Specifications (F2700)

### Battery Specifications (F2804)

The IPG’s internal battery shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0850 | The IPG shall use the following rechargeable battery:  Manufacturer:  **Greatbatch Medical**  Model Number:  **2993**  Nominal Capacity:  **215mA·h** |
| FRS0851 | Maximum Battery Voltage, Fully Charged, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 4.093 | 4.100 | 4.107 | |
| FRS0852 | Battery 75% Voltage Threshold, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.945 | 3.950 | 3.955 | |
| FRS0853 | Battery 75% Voltage Threshold, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.920 | 3.925 | 3.930 | |
| FRS0854 | Battery 50% Voltage Threshold, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.845 | 3.850 | 3.855 | |
| FRS0855 | Battery 50% Voltage Threshold, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.820 | 3.825 | 3.830 | |
| FRS0856 | Battery 25% Voltage Threshold, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.775 | 3.780 | 3.785 | |
| FRS0857 | Battery 25% Voltage Threshold, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.750 | 3.755 | 3.760 | |
| FRS0858 | Battery Warning Voltage Threshold, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.735 | 3.740 | 3.745 | |
| FRS0859 | Battery Warning Voltage Threshold, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.710 | 3.715 | 3.720 | |
| FRS0860 | Battery Critical Voltage Threshold, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.715 | 3.720 | 3.725 | |
| FRS0861 | Battery Critical Voltage Threshold, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.690 | 3.695 | 3.700 | |
| FRS0862 | Minimum Safe Stimulating Voltage, No Load   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.695 | 3.700 | 3.705 | |
| FRS0863 | Minimum Safe Stimulating Voltage, Stimulation On   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 3.670 | 3.675 | 3.680 | |
| FRS0865 | Battery Cut-Off Voltage Threshold   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 2.750 | 2.850 | 2.950 | |
| FRS0866 | Maximum Battery Load Current   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | - | - | 215 | |
| FRS0867 | Maximum Recharging Current   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | mA | - | - | 107 | |
| FRS0868 | Battery Over-Voltage Protection Clamp   |  |  |  |  | | --- | --- | --- | --- | | **Unit** | **Min** | **Typ** | **Max** | | V | 4.170 | 4.200 | 4.230 | |
| FRS0873 | The battery shall maintain at least 50% of its original capacity after five deep discharges below 2.75V. |
| FRS0872 | The IPG shall record the number of times that it enters Storage Mode as a result of the battery reaching its cutoff voltage. |
| FRS0871 | The battery shall be capable of withstanding more than 1,000 full charge/discharge cycles, with the battery's capacity being greater than 50% of its original capacity at the 1,000th cycle. |
| FRS0870 | The IPG and its battery shall tolerate partial discharges and recharges. |
| FRS0869 | The IPG shall be shipped from the factory with a battery Voltage of 4.00V or greater. |

### Battery Protection (F2807)

The IPG shall have the following features for protecting the battery:

| **ID** | **Title** |
| --- | --- |
| FRS0875 | The IPG shall include a battery protection switch that can disconnect the battery from the IPG hardware. |
| FRS0876 | The IPG shall include over-voltage protection to protect the battery from voltages greater than 4.20V during recharge. |

### Battery Monitor (F2815)

The IPG shall have a battery monitor feature to determine the battery’s remaining capacity.  The battery monitor shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0877 | The battery monitor shall have the following states: Battery ≥ 75%: This state indicates that the battery’s capacity is at 75% or greater. |
| FRS0878 | The battery monitor shall have the following states: 75% > Battery ≥ 50%: This state indicates that the battery’s capacity is less than 75% and greater than or equal to 50%. |
| FRS0879 | The battery monitor shall have the following states: 50% > Battery ≥ 25%: This state indicates that the battery’s capacity is less than 50% and greater than or equal to 25%. |
| FRS0880 | The battery monitor shall have the following states: Battery Warning: This state indicates that the IPG needs to be recharged soon. |
| FRS0881 | The battery monitor shall have the following states: Battery Critical: This state indicates that the IPG is nearing the point of shutting off stimulation. |
| FRS0882 | The battery monitor shall have the following states: Battery Too Low for Stimulation: This state indicates that the IPG has shut off stimulation due to a low battery. |
| FRS0883 | Each of the states above shall have two thresholds (listed in the Battery Specifications table) to measure against. One threshold shall be used for when stimulation is off while the other shall be used for stimulation is on. |
| FRS0884 | If the IPG is not in Recharge Mode, when the battery monitor enters a state it shall not return to a higher state. |
| FRS0886 | If the IPG is in Storage Mode, battery monitoring sampling cannot occur. |
| FRS0887 | If the IPG is powered but stimulation is off, the battery monitor shall sample the battery voltage at least once every 24 hours regardless of the battery monitor state. |
| FRS0888 | If stimulation is on and the battery monitor is in the Battery ≥ 75% or Battery ≥ 50% states, the battery monitor shall sample the battery voltage at least once every 4 hours. |
| FRS0889 | If stimulation is on and the battery monitor is in the Battery ≥ 25% or Battery Warning states, the IPG shall sample the battery voltage at least once every 1 hour. |
| FRS0890 | If stimulation is on and the battery monitor is in the Battery Critical state, the IPG shall sample the battery voltage at least once every 15 minutes. |
| FRS0891 | If stimulation is on and the battery monitor enters the Battery Too Low for Stimulation state, the IPG shall turn off stimulation upon completion of the current program cycle. |
| FRS0892 | The IPG shall be able to provide the battery monitor state on command from an external programming device. |
| FRS0893 | If the IPG measures a battery voltage at or below the Battery Cutoff Voltage, it shall put the IPG into Storage Mode. Prior to doing so, it shall set a flag indicating the IPG entered Storage Mode due to low battery. |

### Inductive Power Link (F2816)

The IPG shall have an inductive link for transcutaneous power transfer.  The inductive link shall have two modes of operation: engaged and disengaged.  The inductive link shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0894 | Receiving power over the inductive link shall be capable of bringing the IPG out of Storage Mode. |
| FRS0895 | Power transfer over the inductive link shall not interfere with MICS communications. |
| FRS0896 | Power transfer over the inductive link shall not disrupt the stimulation output. |
| FRS0897 | When disengaged, the inductive link shall become engaged when the IPG receives 0.30W (±5%) of power or more. |
| FRS0898 | When engaged, the inductive link shall become disengaged when the IPG receives less than the minimum power required for the given recharge phase. |
| FRS0899 | After the inductive link transitions from disengaged to engaged, the IPG shall initiate the recharge process. |
| FRS0901 | The IPG shall be capable of measuring the DC voltage received over the inductive link. If the IPG detects that the power is too low to continue recharging or that the inductive link has become disengaged, it shall cease the charging process by disabling the charge controller. |

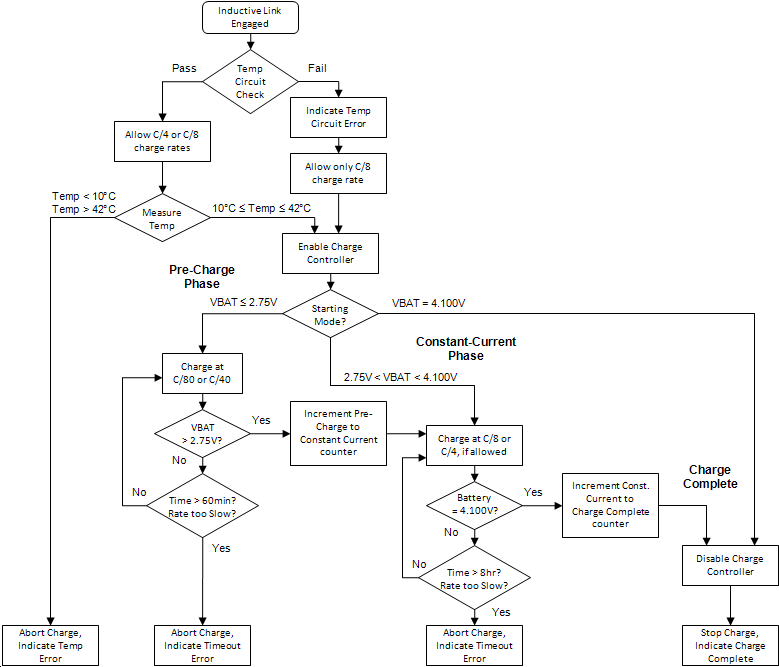
#### Inductive Link Electrical Specifications (F5868)

The inductive link shall have the following electrical specifications:

| **ID** | **Title** |
| --- | --- |
| FRS1193 | The IPG shall have an internal coil for power transfer. This coil shall be tuned to 40kHz ±1kHz. |
| FRS1194 | The inductive link shall be capable of receiving up to 1.0W for recharging power. The link shall be capable of receiving up to an addition 1.0W (for a total of 2.0W) without damaging the internal electronics. |

### Recharging (F5873)

The IPG’s recharging process shall behave as follows:



| **ID** | **Title** |
| --- | --- |
| FRS0902 | The IPG’s recharging process shall consist of four distinct phases. A list of the phases showing the process can be found below:   1. Initiation of Charging Process 2. Pre-Charge Phase 3. Constant-Current Phase 4. Completion of Charging Process |
| FRS0907 | If the inductive link becomes disengaged during any point of the charging process, the IPG shall stop the charging process. Re-engaging the inductive link shall cause the IPG to return to the temperature measurement circuit diagnostic. |
| FRS0908 | The IPG shall have a counter that is incremented every time the charging process transitions from Pre-Charge Phase to Constant-Current Phase. This counter shall be able to count to at least 10,000. |
| FRS0910 | The IPG shall have a counter that is incremented every time the charging process transitions from Constant-Current Phase to the end of Charge Complete. This counter shall be able to count to at least 2000. |

#### Initiation of Charging Process (F5889)

For the Initiation of Charging Process phase, the IPG shall perform the following steps:

| **ID** | **Title** |
| --- | --- |
| FRS0911 | After the inductive link becomes engaged, the IPG shall run a temperature measurement circuit diagnostic check. If the diagnostic check passes, the IPG shall allow a charge rate of C/4. If the diagnostic check fails, the IPG shall indicate a temperature circuit error to the external charger and shall be limited to a charge rate of C/8 at all times. |
| FRS0912 | The IPG shall measure the internal temperature. It shall only proceed to the next step if the IPG’s internal temperature is less than 42°C ±0.5°C and greater than 10°C ±2°C. If the temperature is outside this range, the IPG shall indicate a temperature out-of-range error to the external charger. |
| FRS0913 | The IPG shall enable the charge controller, which will begin the charging process in either the Pre-Charge phase, the Constant-Current phase, or the Charge Complete phase depending on battery voltage. The charge controller shall automatically determine which phase to enter. |
| FRS0914 | If the temperature measurement circuit passed the diagnostic check in the first step above, the IPG shall start the charging process at a C/4 rate. If the temperature measurement diagnostic failed, the IPG shall start the charging process at a C/8 rate. |

#### Pre-Charge Phase (F5890)

The Pre-Charge phase shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0917 | The charge controller shall remain in the Pre-Charge phase until the battery voltage reaches 2.75V. |
| FRS0918 | The maximum current delivered to the battery in this phase shall be 5.50mA. |
| FRS0920 | While in this phase, the IPG shall sample the battery voltage every 5min ±30s. If the IPG does not detect a battery voltage increase of 25mV or more between samples, it shall abort the charging process. |
| FRS0921 | If the IPG detects that it has been in this phase for more than 60 minutes, it shall abort the charging process. |

#### Constant-Current Phase (F5891)

The Constant-Current phase shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0922 | The charge controller shall remain in the Constant-Current phase until the battery voltage reaches full capacity (4.1V). |
| FRS0923 | The maximum current delivered to the battery in this phase shall be 55mA. |
| FRS0924 | While in this phase, the IPG shall sample the battery voltage every 5min ±30s. If the IPG does not detect a battery voltage increase of 8mV in at least 1 out of 12 samples, it shall abort the charging process. |
| FRS0925 | If the IPG detects that it has been in this phase for more than 8 hours, it shall abort the charging process. |
| FRS1224 | While in the Constant-Current phase, the IPG shall be capable of switching between discrete charge rates of C/4 or C/8. |

#### Completion of Charging Process (F5894)

The IPG shall handle the following scenarios for aborting or completing the charging process:

| **ID** | **Title** |
| --- | --- |
| FRS0931 | The inductive link becomes disengaged and remains disengaged for more than 20s. |
| FRS0932 | The IPG detects that the battery voltage is not increasing during the Pre-Charge Phase. |
| FRS0933 | Pre-Charge Phase takes longer than its maximum time. |
| FRS0934 | The IPG detects that the battery voltage is not increasing during the Constant-Current Phase. |
| FRS0935 | Constant-Current Phase takes longer than its maximum time. |
| FRS0936 | The Charge Complete Phase is successfully achieved. |
| FRS0937 | The IPG detects a high temperature as described in the Temperature Measurement section. |
| FRS0939 | For all scenarios, the IPG shall perform the following steps to stop the charging process: 1  1.  The IPG shall disable the charge controller if it is enabled. |
| FRS1203 | For all scenarios, the IPG shall perform the following steps to stop the charging process: 2.  2.  The IPG shall return data to the external charger indicating that charging has stopped and that inductive power must be turned off. |
| FRS1204 | For all scenarios, the IPG shall perform the following steps to stop the charging process: 3.  3.  When charging is completed, the IPG shall detune the inductive link by enabling the LSK detuning circuit. The IPG shall remain in this state until the inductive link is disengaged. |

### Temperature Measurement (F5874)

The IPG’s temperature measurement feature shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0942 | The IPG shall have an internal thermistor that is calibrated so that its readings correspond to the external temperature of the enclosure. |
| FRS0943 | The IPG shall be capable of measuring its internal temperature over a range of 35°C to 45°C with a resolution of 0.1°C and an accuracy of ±0.5°C. The IPG shall have an extended temperature range of 0°C to 35°C with a resolution of 1°C and an accuracy of ±1°C. |
| FRS0944 | When the inductive link is engaged, the IPG shall sample the temperature at least once every 5s. |

### Charging Rate Control (F8516)

The IPG shall have the ability to adjust the charging rate as follows:

| **ID** | **Title** |
| --- | --- |
| FRS1225 | If the IPG measures an internal temperature that correlates to an enclosure outer temperature greater than or equal to 41.0°C ±0.5°C, the IPG shall force the charge controller to operate at a charge rate of C/8. |
| FRS1226 | If the IPG measures an internal temperature that correlates to an enclosure outer temperature greater than or equal to 42.0°C with an accuracy range ± 0.5°C, the IPG shall abort the charging process. |
| FRS1227 | If the IPG is charging at a rate of C/8 and measures a temperature less than 40.0°C ±0.5°C, the IPG shall adjust the charge rate to C/4. This shall only be possible if the temperature measurement circuit was functional when the inductive link was initially engaged. |
| FRS1228 | When the inductive link is initially engaged, if the temperature diagnostic check passes, the IPG shall initiate charging at the C/4 rate. If the check fails, the IPG shall initiate charging at the C/8 rate. |

### Elective Replacement Indicator (F7265)

The elective replacement indicator provides a means to let the user know when it may be necessary to replace the IPG.  This indicator has the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0951 | The IPG shall be capable of storing its date of implant as set by an external programmer. The IPG shall store this date in non-volatile memory. |
| FRS0952 | The IPG shall be capable of storing an elective replacement interval as set by an external programmer. The IPG shall store this interval in non-volatile memory.  The default value for this interval shall be 120 months. |
| FRS0953 | The IPG shall be capable of providing the date of implant and elective replacement interval when requested by an external programmer. |

## Communications with External Devices (F2701)

### MICS Link Characteristics (F2754)

The MICS link shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0954 | All communications over the MICS link shall be initiated by an external device. The IPG shall not initiate any MICS communications. |
| FRS0955 | The MICS link shall function over a range of at least 100cm between the IPG and the external device for an IPG implant depth of 0.5cm to 1.5 cm deep. The MICS link shall function over a range of at least 30cm between the IPG and the external device for an IPG implant depth of 1.5 to 2.5 cm deep. |
| FRS0958 | MICS communications shall not interfere with the IPG’s stimulation output. The stimulation output shall remain within specification while messages are being received by the IPG. |
| FRS0959 | The IPG shall reply to every command from an external device to verify the successful or unsuccessful execution of the command. |
| FRS0960 | The IPG shall have the capability to retune the MICS circuit on demand to compensate with time related changes such as fluid ingress into the IPG header. |

### MICS Pairing (F5924)

Pairing shall be used to improve the security of MICS communications.  This feature shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS0961 | The IPG shall have a unique MICS address. This address shall be programmed during manufacturing and shall be used by the MICS protocol to identify the IPG during the initiation of messages. |
| FRS0962 | The IPG shall be paired to up to two Pocket Programmers. It shall return an error code if it receives a command from an unpaired PoP. |
| FRS0963 | The IPG shall be paired to one Patient Programmer/Charger. It shall return an error code if it receives a command from an unpaired PPC. |
| FRS0964 | The IPG shall accept commands from any Clinician Programmer. |
| FRS0965 | The IPG shall be capable of being paired with new PoPs or PPCs. |
| FRS1229 | The IPG shall be capable of being paired to a PoP or PPC using a command sent via unpaired MICS communications. |

### Unpaired MICS Communications (F8515)

The IPG shall have a means of communicating with the External Charger via an unpaired MICS link. This link shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS1230 | Unpaired MICS communications shall be initiated using the 400MHz MICS wakeup signal. The inductive link must be engaged for this to occur. |
| FRS1231 | All messages between the External Charger and IPG shall be initiated by the charger. The IPG shall send data back in response to charger commands. |
| FRS1232 | Unpaired MICS communications shall work over the same range as paired MICS communications. |
| FRS1233 | The IPG shall be capable of responding to the following commands over the unpaired MICS link:   1. Returning inductive power status 2. Returning internal temperature information 3. Returning IPG status |

### MICS Commands (F2757)

The MICS communications link shall use the following sets of commands to control the IPG:

#### Commands for Operational Status

The IPG shall support commands for obtaining the operational status of the IPG:

| **ID** | **Title** |
| --- | --- |
| FRS0966 | Returning the IPG’s current status |
| FRS0967 | Returning one or more of the IPG’s internal constants and settings |
| FRS0968 | Returning one or more of the IPG’s program or pulse names |
| FRS0969 | Returning program runtime counters |

#### Commands for Stimulation Output

The IPG shall support commands for updating the IPG’s stimulation output:

| **ID** | **Title** |
| --- | --- |
| FRS0970 | Turning stimulation on/off |
| FRS0971 | Selecting a program |
| FRS0972 | Control of pulse or program amplitude |
| FRS0973 | Control of pulse width |
| FRS0974 | Control of program frequency |
| FRS0975 | Restoring program stimulation parameters to default setting |
| FRS0976 | Resetting program runtime counters |

#### Commands for Controlling Recharging

The IPG shall support commands for control of recharging:

| **ID** | **Title** |
| --- | --- |
| FRS0977 | Starting or stopping recharging |
| FRS0978 | Returning recharge status, inductive link voltage, or IPG internal temperature |
| FRS0979 | Returning charging counter values |

#### Commands for MICS Communication

The IPG shall support commands for MICS communications:

| **ID** | **Title** |
| --- | --- |
| FRS0980 | Setting or returning the IPG’s model number, serial number, or MICS ID |
| FRS0982 | Setting or returning pairing information for two PoPs and one PPC |

#### Commands for Pulse and Program Definitions

The IPG shall support commands for pulse and program definitions:

| **ID** | **Title** |
| --- | --- |
| FRS0984 | Deleting pulses or programs |
| FRS0985 | Setting or returning program definitions |
| FRS0987 | Setting or returning stimulation parameter constants |

#### Commands for Test and Titration Stimulation

The IPG shall support commands for test and Titration Stimulation:

| **ID** | **Title** |
| --- | --- |
| FRS0988 | Setting or returning test pulse and program definitions |
| FRS0989 | Setting or returning titration pulse and program definitions |
| FRS0990 | Starting or stopping test or titration stimulation |

#### Commands for Diagnostic or Configuration

The IPG shall support commands for diagnostic or configuration purposes:

| **ID** | **Title** |
| --- | --- |
| FRS0991 | Forcing the IPG into Storage Mode |
| FRS0992 | On-demand impedance measurement |
| FRS0993 | Diagnostic temperature measurements |
| FRS0994 | Returning or clearing the IPG’s event log |
| FRS0995 | Returning or clearing the IPG’s error log |
| FRS0997 | Setting or returning lead information |
| FRS0998 | Setting or returning charge density or current density limits |
| FRS0999 | Setting or returning calibration constants |
| FRS1000 | Setting or returning configuration settings |
| FRS1001 | Setting or returning patient information |
| FRS1002 | Setting or returning date of implant and elective replacement interval |
| FRS1003 | Putting the IPG into Bootloader Mode |
| FRS1004 | Disabling, enabling, or adjusting background impedance measurements |

#### Commands for Testing Purposes

The IPG shall support commands for testing purposes:

| **ID** | **Title** |
| --- | --- |
| FRS1234 | Echoing known data back to an external device |
| FRS1005 | Returning battery voltage level |
| FRS1006 | Returning inductive link voltage level |
| FRS1236 | Returning background impedance check data |
| FRS1237 | Direct read and write of IPG memory locations and registers |

## Diagnostics (F2702)

### Background Impedance Measurement (F2736)

Background impedance measurements are performed by the IPG when stimulation is off.  The primary purpose of this feature is to detect an open-circuit condition for one or more of the IPG’s output channels.  This feature shall have the following specifications:

| **ID** | **Title** |
| --- | --- |
| FRS1007 | When enabled, a background impedance measurement shall be performed every time a stimulation program is stopped. |
| FRS1008 | Each background impedance measurement shall measure the impedance between the IPG’s enclosure and each output channel that was used in the program just stopped. |
| FRS1010 | The default pulse parameters for background impedance measurement shall be as follows. The amplitude shall be adjustable:   1. Stimulus Phase Amplitude: 200uA (default) or 100uA 2. Stimulus Phase Pulse Width:  200us 3. Number of pulses:  4 |
| FRS1013 | The IPG shall flag a channel as an open-circuit if the load impedance between that channel and the enclosure is 5000Ω ±500Ω resistive or greater. If one or more channels are flagged as open-circuit during a background impedance check, the IPG shall respond as described in the Fault Detection and Recovery section. |
| FRS1014 | The background impedance measurement shall be capable of being configured as enabled or disabled via a command from an external programmer. By default, this feature shall be enabled. |

### Impedance Measurement on Demand (F2738)

The IPG shall have the ability to measure the impedance between any two channels on command from an external device.  This feature shall have the following characteristics:

| **ID** | **Title** |
| --- | --- |
| FRS1015 | The IPG shall have a set of constants that pertain to the stimulation parameters used during on-demand impedance measurement. These constants shall be as follows:   1. Impedance Measurement Amplitude:  500 uA  or 200uA (default) 2. Impedance Measurement Pulse Width:  200 us 3. Impedance Measurement Number of Pulses per Measurement: 4 |
| FRS1022 | If a program is actively running at the time the IPG receives an on-demand impedance measurement command, it shall return an error code to the external programmer. If no program is running, the IPG shall proceed with the desired measurement. |
| FRS1023 | To perform the impedance measurement, the IPG shall put out the number of pulses specified in the “Number of Pulses per Measurement” field. |
| FRS1024 | The IPG shall return the impedance value as the average of all measured pulses. |
| FRS1025 | The IPG shall be capable of measuring impedance over a range of 100Ω to 7000Ω with an accuracy as follows:     |  |  |  | | --- | --- | --- | | **Range** | **Accuracy, 200uA Setting** | **Accuracy, 500uA Setting** | | 100-1500 Ω | ±100Ω | ±100Ω | | 1500-5000 Ω | ±250Ω | - | | 5000-7000 Ω | ±500Ω | - | |

### Reserved (F5936)

### Verification of Temperature Measurement Circuitry (F2739)

The IPG shall have the ability to verify that the temperature measurement circuit is free of faults.  This feature shall have the following specifications:

| **ID** | **Title** |
| --- | --- |
| FRS1033 | The IPG shall have the ability to independently measure the voltage across all of the physical components in the temperature measurement circuit. If any of the components provides a voltage that is outside of its expected range, the IPG shall indicate an error. |
| FRS1035 | If an error is detected during the voltage check, the IPG shall log the error. |

### Verification of System Clocks (F2740)

The IPG shall have the ability to check timing related to stimulation as follows:

#### System Clock Checks (F5937)

[RESERVED]

#### Stimulation Clock Checks (F5938)

The IPG shall have the ability to verify the operation of various clocks related to stimulation.  This diagnostic shall have the following features:

| **ID** | **Title** |
| --- | --- |
| FRS1041 | Prior to starting stimulation, the IPG shall verify that the pulse guard is working correctly. If the pulse guard fails, the IPG shall not allow stimulation to be started. |
| FRS1042 | Once stimulation is running, the IPG shall verify that the stimulation program period is correct. |

### Memory Corruption Detection (F2741)

The IPG shall have the ability to determine when memory has been compromised.  The following types of memory shall be monitored as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1045 | The IPG firmware shall be monitored by the Internal Watchdog described in the Stimulation Safety Mechanisms section. This feature shall reset the IPG if firmware corruption causes the device to malfunction. At a minimum, the watchdog shall be active during Stimulation and Recharge modes. |
| FRS1046 | All program definitions shall be monitored for data corruption. Each program definition shall be verified prior to being accessed for setting up stimulation or returning data to an external programmer. |
| FRS1047 | All active stimulation settings shall be monitored for data corruption. Active stimulation settings for a program shall be verified prior to being accessed for setting up stimulation or returning data to an external programmer. |
| FRS1048 | All active stimulation settings stored in the Stim ASIC registers shall be monitored for data corruption. The registers shall be monitored continuously by the Stim ASIC for parity errors while stimulation is active. |
| FRS1049 | The MICS identity information shall be monitored for data corruption and shall be verified every time a MICS session is initiated by an external programmer. |
| FRS1050 | All program constants shall be monitored for data corruption. The constants for each program shall be verified prior to being accessed for setting up stimulation or returning data to an external programmer. |
| FRS1051 | All pulse constants shall be monitored for data corruption. The constants for each pulse shall be verified prior to being accessed for setting up stimulation or returning data to an external programmer. |
| FRS1052 | All electrode limits shall be monitored for data corruption. The limits shall be verified prior to being accessed for setting up stimulation or returning data to an external programmer. |
| FRS1053 | All lead information shall be monitored for data corruption. The lead information shall be verified prior to being accessed by the firmware. |
| FRS1054 | All configurable device parameters shall be monitored for data corruption. The parameters shall be verified prior to being accessed by the firmware. |
| FRS1055 | All calibration data shall be monitored for data corruption. The calibration data shall be verified prior to being accessed by the firmware. |

### [reserved]

[reserved]

## Fault Detection and Recovery (F2696)

Errors shall be handled by the IPG in the following manner:

a.  Errors shall be defined in three categories as defined in SWEX 0091.  The categories are broken down as follows:

1. Category 1 errors shall consist of errors or faults that prevent the IPG from providing stimulation to the patient.
2. Category 2 errors shall consist of faults that require clinician intervention to resolve, but may allow the IPG to provide stimulation to the Patient in a limited manner.
3. Category 3 errors shall consist of faults that the IPG can resolve itself or through interaction with an external programmer.

b.  Errors related to charging shall be reported separately from command errors.

### Active Error Handling (F8397)

The IPG shall act on errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1238 | The IPG shall retain the latest error of each category internally. |
| FRS1239 | Category 3 errors shall be cleared after being returned in response to a status command response or cleared when the IPG enters Storage mode. |
| FRS1240 | Category 2 errors shall indicate whether one or more stimulation programs are disabled. These errors shall be stored in non-volatile memory so that they are not cleared when the IPG enters Storage mode. |
| FRS1241 | Category 1 errors shall be cleared if the IPG enters Storage mode. |
| FRS1242 | The IPG shall return the most severe error code when queried by an external programmer. An error of lower severity shall not supplant an error of higher severity. If two errors of the same severity are present, the most recent error shall be returned. |

### Command Errors (F5927)

The IPG shall recover from the following command errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1059 | Requested Program Invalid  **Fault:**  An external device requests the initiation of a program that is either invalid or disabled.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested program is invalid.  The IPG shall not allow the invalid program to be started. |
| FRS1060 | Current Density Limit Error  **Fault:**  An external device requests an amplitude setting that exceeds the current density limit for one or more channels.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested amplitude is not allowed.  The IPG shall not adjust the stimulation to the requested amplitude. |
| FRS1061 | Charge Density Limit Error  **Fault:**  An external device requests an amplitude or pulse width setting that exceeds the charge density limit for one or more channels.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested amplitude or pulse width is not allowed.  The IPG shall not adjust the stimulation to the requested amplitude or pulse width. |
| FRS1062 | Amplitude Increase Not Allowed  **Fault:**  An external device requests an amplitude increase when the IPG is already set to the maximum allowable amplitude.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested amplitude is not allowed.  The IPG shall not adjust the stimulation to the requested amplitude. |
| FRS1063 | Amplitude Decrease Not Allowed  **Fault:**  An external device requests an amplitude decrease when the IPG is already set to the minimum allowable amplitude.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested amplitude is not allowed.  The IPG shall not adjust the stimulation to the requested amplitude. |
| FRS1064 | Pulse Width Increase Not Allowed  **Fault:**  An external device requests a pulse width increase when the IPG is already set to the maximum allowable pulse width.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested pulse width is not allowed.  The IPG shall not adjust the stimulation to the requested pulse width. |
| FRS1065 | Pulse Width Decrease Not Allowed  **Fault:**  An external device requests a pulse width decrease when the IPG is already set to the minimum allowable pulse width.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested pulse width is not allowed.  The IPG shall not adjust the stimulation to the requested pulse width. |
| FRS1066 | Frequency Increase Not Allowed  **Fault:**  An external device requests a frequency increase when the IPG is already set to the maximum allowable frequency.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested frequency is not allowed.  The IPG shall not adjust the stimulation to the requested frequency. |
| FRS1067 | Frequency Decrease Not Allowed  **Fault:**  An external device requests a frequency decrease when the IPG is already set to the minimum allowable frequency.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested frequency is not allowed.  The IPG shall not adjust the stimulation to the requested frequency. |
| FRS1068 | Command Not Allowed Due to Increment Rate Lockout  **Fault:**  An external device requests an increase in amplitude, pulse width, or frequency while the increment rate lockout duration is active.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested increase is not allowed.  The IPG shall not adjust the stimulation. |
| FRS1069 | Command Not Allowed Due to Ramping  **Fault:**  An external device requests an increase or decrease in amplitude, pulse width, or frequency while ramping is active at the start of a program.  **Recovery:**  The IPG shall return an error code to the external device stating that the requested increase or decrease is not allowed.  The IPG shall maintain the original stimulation parameters at the conclusion of the ramp. |
| FRS1070 | Command from an Unpaired Device  **Fault:**  An external device that is not paired with the IPG sends a command to the IPG’s MICS address.  **Recovery:**  The IPG shall return an error code to the external device stating that it cannot execute the command because the devices are not paired. |
| FRS1071 | On-Demand Impedance Command While Stimulation Active  **Fault:**  An external device requests an on-demand impedance measurement while a program is actively running on the IPG.  **Recovery:**  The IPG shall return an error code to the external device stating that it cannot execute the command because stimulation is active. |

### Data Errors (F5928)

The IPG shall recover from the following data errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1072 | Program Data Integrity Error  **Fault:**  Prior to starting a program, the IPG detects a problem with the integrity of data related to stimulation output.  **Recovery:**  An error code shall be returned to the external device and the program shall not be allowed to start. |
| FRS1073 | Stimulation Data Read-Back Error  **Fault:**  After writing data to the Stim ASIC, there is an error during data read-back.  **Recovery:**  The IPG shall halt the stimulation update, log the error, and reset itself. |
| FRS1074 | Program Definition Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that a program definition has been corrupted.  **Recovery:**  The IPG shall set the corrupted program as invalid and log the error.  The IPG shall return an error code the next time it receives a message from an external device. |
| FRS1075 | Active Stimulation Settings Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that stimulation data stored in memory or being actively used by the Stim ASIC is corrupted.  **Recovery:**  If stimulation is active, the IPG shall stop stimulation and log the error. The IPG shall allow stimulation to be restarted by a command from an external device. |
| FRS1076 | MICS Identity Information Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that MICS identity information is corrupted.  **Recovery:**  The IPG shall log the error.  The IPG shall store multiple copies of the MICS ID in different areas of the memory map and shall use these copies to restore the corrupted ID. |
| FRS1077 | Program Constants Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that program constants are corrupted.  **Recovery:**  The IPG shall set all programs as invalid and log the error.  The IPG shall return an error code the next time it receives a message from an external device. |
| FRS1078 | Pulse Constants Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that pulse constants are corrupted.  **Recovery:**  The IPG shall set all programs as invalid and log the error.  The IPG shall return an error code the next time it receives a message from an external device. |
| FRS1079 | Electrode Limits Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that electrode limits are corrupted.  **Recovery:**  The IPG shall set all programs as invalid and log the error.  The IPG shall return an error code the next time it receives a message from an external device. |
| FRS1080 | Lead Information Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that lead information is corrupted.  **Recovery:**  The IPG shall log the error and shall return an error code the next time it receives a message from an external device. |
| FRS1081 | Configurable Device Parameters Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that configurable device parameters are corrupted.  **Recovery:**  The IPG shall log the error.  The IPG shall cease communications with PoPs and PPCs, but shall accept commands from CPs. |
| FRS1082 | Calibration Data Corrupted  **Fault:**  During a diagnostic memory check, the IPG detects that calibration data is corrupted.  **Recovery:**  The IPG shall set all programs as invalid and log the error.  The IPG shall return an error code the next time it receives a message from an external device. |

### Internal Power Errors (F5929)

The IPG shall recover from the following internal power errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1083 | Battery Too Low for Stimulation  **Fault:**  The battery monitor feature detects that the battery is too low to initiate or to continue stimulation.  **Recovery:**  If stimulation is active when the battery monitor detects that the battery is too low, the IPG shall stop the active program and return to Idle Mode.  For any commands that attempt to initiate a program after the battery reaches this point, the IPG shall return an error code and shall not allow the program to be started. |
| FRS1087 | Battery Voltage Reaches Cutoff Level  **Fault:**  The fuel gauge feature detects that the battery has reached the cutoff level.  **Recovery:**  If the battery reaches the cutoff level, the IPG shall set a flag indicating the IPG is entering Storage Mode due to reaching the battery cutoff level.  The IPG shall then transition to Storage Mode. |

### Stimulation Output Errors (F5930)

The IPG shall recover from the following stimulation output errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1090 | Pulse Guard Trips During Active Stimulation, Step 1  **Fault:**  The IPG’s pulse guard feature is tripped during active stimulation.  **Recovery:** When this problem occurs, the IPG shall perform the following steps:  1.    The IPG shall disable the stimulation hardware. |
| FRS1092 | Pulse Guard Trips During Active Stimulation, Step 2  **Fault:**  The IPG’s pulse guard feature is tripped during active stimulation.  **Recovery:**  When this problem occurs, the IPGF shall perform the following steps  3.       The IPG shall log an error stating a pulse guard trip occurred. |
| FRS1093 | Pulse Guard Trips During Active Stimulation, Step 3  **Fault:**  The IPG’s pulse guard feature is tripped during active stimulation.  **Recovery:**  When this problem occurs, the IPGF shall perform the following steps:  4.       The IPG shall allow an external device to re-initiate stimulation. |
| FRS1095 | Background Impedance Measurement Diagnostic Detects an Open Circuit Condition, Step 1  **Fault:**  The IPG’s background impedance measurement diagnostic detects an open circuit condition on one or more output channels.  **Recovery:** When the IPG detects an open circuit condition during a background impedance check, it shall perform the following steps: Step 1  1.  For every program that uses the affected channel(s), the IPG shall set the program as disabled to prevent it from being initiated by an external device. |
| FRS1096 | Background Impedance Measurement Diagnostic Detects an Open Circuit Condition, Step 2  **Fault:**  The IPG’s background impedance measurement diagnostic detects an open circuit condition on one or more output channels.  **Recovery:**  When the IPG detects an open circuit condition during a background impedance check, it shall perform the following steps:  2.       The IPG shall log the open condition in the error log. |
| FRS1097 | Background Impedance Measurement Diagnostic Detects an Open Circuit Condition, Step 3  **Fault:**  The IPG’s background impedance measurement diagnostic detects an open circuit condition on one or more output channels.  **Recovery:**  When the IPG detects an open circuit condition during a background impedance check, it shall perform the following steps:  3.  The IPG shall return an error code to an external device. |

### Firmware Errors (F5931)

The IPG shall recover from the following firmware errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1104 | Internal Watchdog is Tripped While Stimulation is Active, Step 1  **Fault:**  During active stimulation, the IPG’s internal watchdog is tripped.  **Recovery:** When the IPG detects this problem, it shall perform the following steps:  1.    The IPG shall stop stimulation within 250us of the watchdog event. |
| FRS1105 | Internal Watchdog is Tripped While Stimulation is Active, Step 2  **Fault:**  During active stimulation, the IPG’s internal watchdog is tripped.  **Recovery:**  When the IPG detects this problem, it shall perform the following steps:  2.       The IPG shall log an error stating that a watchdog error has occurred. |
| FRS1106 | Internal Watchdog is Tripped While Stimulation is Active, Step 3  **Fault:**  During active stimulation, the IPG’s internal watchdog is tripped.  **Recovery:**  When the IPG detects this problem, it shall perform the following steps:  3.       After coming out of reset, the IPG shall remain in Idle Mode and shall not reinitiate stimulation. |

### Recharging Errors (F5932)

The IPG shall recover from the following recharging errors as described below:

| **ID** | **Title** |
| --- | --- |
| FRS1108 | Temperature Too High to Initiate Recharge  **Fault:**  When initiating a recharge, the temperature measurement feature determines that the IPG is too hot to initiate a recharge.  **Recovery:**  The IPG shall return an error code to the PPC indicating that the IPG’s temperature is too high to initiate recharge. This error shall be cleared by reinitiating charging. |
| FRS1109 | Too Much Time Spent in Precharge Phase  **Fault:**  The IPG detects that it has spent too much time in the Precharge phase of recharge.  **Recovery:**  The IPG shall return an error code to the PPC indicating that the Precharge phase has taken too long and that recharging must be stopped. This error shall be cleared by reinitiating charging. |
| FRS1110 | Insufficient Progress During Precharge Phase  **Fault:**  The IPG detects that battery charging is not progressing properly during the Precharge phase.  **Recovery:**  The IPG shall return an error code to the PPC indicating that the Precharge progress is insufficient and that recharging must be stopped. This error shall be cleared by reinitiating charging. |
| FRS1111 | Too Much Time Spent in Constant-Current Phase  **Fault:**  The IPG detects that it has spent too much time in the Constant-Current phase of recharge.  **Recovery:**  The IPG shall return an error code to the PPC indicating that the Constant-Current phase has taken too long and that recharging must be stopped. This error shall be cleared by reinitiating charging. |
| FRS1112 | Insufficient Progress During Constant-Current Phase  **Fault:**  The IPG detects that battery charging is not progressing properly during the Constant-Current phase.  **Recovery:**  The IPG shall return an error code to the PPC indicating that the Constant-Current progress is insufficient and that recharging must be stopped. This error shall be cleared by reinitiating charging. |
| FRS1115 | Temperature Too High to Continue Charging  **Fault:**  The temperature measurement circuit detects that the enclosure temperature is so high that recharging must be stopped.  **Recovery:**  The IPG shall return an error code to the PPC indicating that charging must be stopped immediately. |
| FRS1117 | Thermistor Fault Detected  **Fault:**  The thermistor diagnostic detects a fault in the temperature measurement circuit.  **Recovery:**  The IPG shall log the error then return an error code the next time it receives a command from the external charger. |

### Clock Verification Errors (F5939)

The IPG shall respond to clock verification errors in the following manner:

| **ID** | **Title** |
| --- | --- |
| FRS1122 | Pulse Guard Error Detected  **Fault:**  A problem with the pulse guard timing is detected during stimulation start.  **Recovery:**  The IPG shall log the error and return an error code on the next command from an external device. |
| FRS1123 | Stimulation Timing Error Detected, Step 1  **Fault:**  While stimulation is active, the stimulation program period detects a problem with stimulation timing.  **Recovery:** The IPG shall perform the following steps:  1.    The IPG shall stop stimulation at the end of the program cycle. |
| FRS1124 | Stimulation Timing Error Detected, Step 2  **Fault:**  While stimulation is active, the clock diagnostic check detects a problem with stimulation timing.  **Recovery:**  The IPG shall perform the following steps:  2.       The IPG shall log the error and return an error code on the next command from an external device. |
| FRS1126 | Stimulation Timing Error Detected, Step 3  3.       The IPG shall allow a command from an external device to reinitiate stimulation. |

## Immunity from External Electrical Signals (F2695)

| **ID** | **Title** |
| --- | --- |
| FRS1206 | Defibrillation Compatibility (F89)  The IPG shall be designed so that high-voltage pulses, such as those from an external defibrillator, do not permanently affect the device.  This shall be tested according to specification 20.2 of EN 45502-1:1997.  Following the test, the IPG shall function according to specification. |

### Compatibility with Electrical Cautery Equipment (F86)

The IPG shall withstand high-frequency current from electrical diathermy equipment.

| **ID** | **Title** |
| --- | --- |
| FRS1208 | Electrocautery Compatibility Under Burst Application (F87)  The IPG shall be tested according to section 21.2 of EN 45502-2-1:2003, with the exception that the current shall be distributed across all channels simultaneously.  Following the test, the IPG shall function according to specification. |

## Compatibility with EMI Standards (F2694)

NOTE: For each of the EMI immunity specifications listed in this section, certain exceptions may be added for certain frequencies.  These exceptions shall be described in the EMI test specification.

### RTTE Directive (F2720)

The IPG shall comply with the Radio & Telecommunications Terminal Equipment Directive.

| **ID** | **Title** |
| --- | --- |
| FRS1321 | EN 301 839-2 Compliance (F8534)  The device shall comply with emissions requirements per R&TTE Standard EN 301 839-2 v1.3.1. (402MHz to 405MHz). |
| FRS1161 | EN 301 489 Compliance (F109)  The device shall comply with emissions and immunity requirements per R&TTE Standard EN 301 489-27 v1.1.1. The device sub-classification is 2 for medium reliable communication media per section 6.1.  (402MHz to 405MHz). |
| FRS1244 | EN 300 440-2 Compliance (F8535)  The device shall comply with emissions requirements, receiver spurious only, per R&TTE Standard EN 300 440-2 v1.4.1. |
| FRS1320 | EN 301 489 Compliance  The device shall comply with emissions and immunity requirements, receiver only, per R&TTE Standard EN 301 489-17 v2.2.1. |

### Static Magnetic Fields (F2723)

The IPG shall meet the following requirements with respect to static magnetic fields.

| **ID** | **Title** |
| --- | --- |
| FRS1162 | Exposure to Static 1mT Magnetic Field (F2724)  The IPG shall continue normal operation during and after exposure to a static magnetic field with a flux density of 1mT when tested per ISO 14708-3 §27.103. |
| FRS1163 | Exposure to 10 mT Static magnetic Field (F8552)  The IPG shall be capable of normal operation after exposure to a static magnetic field with a flux density of 10 mT when tested per EN 45502-2-1 §27.7. |
| FRS1245 | Exposure to 50 mT Static Magnetic Field (F2725)  The IPG shall be capable of normal operation during and after exposure to a static magnetic field with a flux density of 50 mT when tested per ISO 14708-3 §27.103. |

### Variable Magnetic Fields (F2726)

The IPG shall meet the following requirements with respect to time-variable magnetic fields.

| **ID** | **Title** |
| --- | --- |
| FRS1164 | A-Line Exposure (F2727)  The IPG shall continue normal operation during and after exposure to magnetic fields ranging from 10 Hz to 30 MHz per ISO 14708-3 §27.104 at the levels specified as “A-line” in Figure 105 of ISO 14708-3. |
| FRS1165 | B-Line Exposure (F2728)  The IPG shall continue normal operation during and after exposure to magnetic fields ranging from 10 Hz to 30 MHz per ISO 14708-3 §27.104 at the levels specified as “B-line” in Figure 105 of ISO 14708-3. |
| FRS1246 | Sinusoidal Field Exposure (F8551)  The IPG shall continue normal operation after exposure to magnetic fields ranging from 1 kHz to 140 kHz per EN 45502-2-1 §27.8 at the levels specified in Figure 107 of EN 45502-2-1. |

### Electromagnetic Fields in Range 30 MHz – 450 MHz (F2729)

The IPG shall meet the following requirements with respect to magnetic fields in the range of 30 MHz to 450 MHz[[1]](http://localhost:51122/V71/GetPage.ase?oThis=d|0x00000016|10586|0|b1fdc|10000&sShowingWhat=Home&sRequest=Documentation" \l "_ftn1" \o "" \t "NewWindow) :

[[1]](http://localhost:51122/V71/GetPage.ase?oThis=d|0x00000016|10586|0|b1fdc|10000&sShowingWhat=Home&sRequest=Documentation" \l "_ftnref1" \o "" \t "NewWindow) ISO 14708-3 §27.105.

| **ID** | **Title** |
| --- | --- |
| FRS1166 | Low Power Conditions (F98)  The IPG shall continue normal operation during and after exposure to electromagnetic fields ranging from 30 MHz to 450 MHz at 16V/m RMS using the test methods and equipment specified by ISO 14708-3 §27.105 and IEC 61000-4-3 with the appropriate modifications. |
| FRS1167 | High Power Conditions (F99)  The IPG shall continue normal operation during and after exposure to electromagnetic fields ranging from 30 MHz to 450 MHz at 140V/m RMS at the specific frequencies of 30, 50, 75, 150, and 450 MHz using the test methods and equipment specified by ISO 14708-3 §27.105 and IEC 61000-4-3, with the appropriate modifications. |

### Protection from EMF in the Range of 450 MHz to 3 GHz (F100)

The IPG shall meet the following requirements with respect to EMF in the range of 450 MHz to 3000 MHz (dipole antenna testing):

| **ID** | **Title** |
| --- | --- |
| FRS1168 | Low Power Conditions (F101)  During and after exposure to electromagnetic fields with frequencies from 450 MHz to 3000 MHz (450, 600, 800, 825, 850, 875, 900, 930, 1610, 1850, 1910, 2450[[1]](http://localhost:51122/V71/GetPage.ase?oThis=d|0x00000016|10586|0|b21bc|10000&sShowingWhat=Home&sRequest=Documentation#_ftn1) , 3000 MHz), at a strength of 40 mW for not less than 15 seconds the device shall remain capable of normal operation (Criteria A).  [[1]](http://localhost:51122/V71/GetPage.ase?oThis=d|0x00000016|10586|0|b21bc|10000&sShowingWhat=Home&sRequest=Documentation#_ftnref1) This may interfere with the Zarlink wake up signal, and therefore preventing true MICS communications (402-405 MHz) from being initiated. |
| FRS1169 | High Power Conditions 450 MHz to 1000 MHz (F102)  During and after exposure to electromagnetic fields with frequencies from 450 MHz to 1000 MHz (450,600,800,825,850,875,900,930 MHz), at a power of 8 W for not less than 15 seconds the device should remain capable of normal operation. |
| FRS1170 | High Power Conditions 1000 MHz to 3000 MHz (F103)  During and after exposure to electromagnetic fields with frequencies from 1000 MHz to 3000 MHz (1610,1850,1910,2450,3000 MHz), at a strength of 2 W for not less than 15 seconds the device should remain capable of normal operation. |

### FCC CFR (F8536)

The IPG shall comply with Federal Communications Commission CFR Part 95.

| **ID** | **Title** |
| --- | --- |
| FRS1247 | FCC Part 15.109 (F8537)  The IPG shall comply with Part 15.109 of the Federal Communications Commission CFR. |
| FRS1248 | FCC Part 95 (F8538)  The IPG shall comply with Part 95 of the Federal Communications Commission CFR |

## Compatibility with Ultrasound and X-Ray (F2693)

### Ultrasound Compatibility (F2717)

| **ID** | **Title** |
| --- | --- |
| FRS1173 | Ultrasound Exposure and Device Durability (F84)  Devices shall remain mechanically intact and capable of normal operation after exposure to diagnostic levels of ultrasonic energy when exposed to one hour of ultrasonic energy at 500W/m^2 with a 50% duty cycle per EN 45502 §22.2 and ISO 14708-1, §22.1. |

### X-Ray Radiation Exposure Requirements (F85)

| **ID** | **Title** |
| --- | --- |
| FRS1175 | X-Ray Radiation Exposure Requirements  The device shall remain mechanically intact and be capable of normal operation after exposure to an absorbed dose of 150 rads (120 kilovolts, 8.5 milliamperes X-Ray tube current). |

# Revision History (F3488)

| **Revision Level** | **Revision Description** | **ECN No#** | **Effective Date** |
| --- | --- | --- | --- |
| 1.1 | Original | 1094 | 10/26/2009 |
| 1.2 | Import into CaliberRM  Major updates to reflect design changes. Per 2010-04-05 letter to file, this is a reset of design controls. | 1134 | 8/9/2010 |
| 1.3 | Remove mechanicals to MESP 0113  Updates per 2011-12-1 design review (EERE 0182 and EERER 0183) | 1638 | 1/15/2013 |
| 1.4 | · Addition of sync phase - F2690, F4941  · Generally rename “fuel gauge” to “battery monitor”  · Solidified diagnostic checks  · Removed Data Save mode and Added bootloader mode F8518  · Clarifying language around magnets (F5926)  · Clarified language around battery charge state changes F2815  · Removed inductive communications F5875, added unpaired MICS F 8515  · Added ability for switching recharge rates F5891, F8516  · Clarified elective replacement interval language F7265  · Clarified diagnostics to match firmware capabilities  · removed MRI conditionality section | 1863 | 07/25/2013 |
| 1.5 | Updated references to reflect what is truly applicable (removed 60601, biocompatibility, sterility)  Amplitude resolution was changed from 15uA to a range of 5uA min to 20uA max  IPG operation was changed to scale the resolution based on the maximum current output, meaning that the resolution is better (5uA) when amplitude is 3.0mA when compared to an amplitude of 15.0mA (20uA resolution)  Resolution scaling was added to help reduce IPG power consumption  Pulse Width resolution was changed from 1us to 4us  Stimulation timing was slowed down from 1MHz to 250kHz to reduce IPG power consumption  Frequency tolerance was relaxed from ±0.15% to ±3.5% to reflects more realistic performance from IPG clock sources  Active recovery waveforms now have a single charge-balance correction (CBC) phase at the end of the program cycle instead of a CBC after each pulse  The formulas for calculating the Recovery Ratio, which determine the amplitude of the active charge balance phase, have been updated  During stimulation, only controlled current sources and sinks will be used  The compliance voltage calculation was updated to reflect using only controlled currents  Test stimulation and titration stimulation definitions updated to reflect implementation  Test stimulation and titration stimulation were separated into different modes  Definitions for each mode were simplified and clarified  Added the ability to enter and exit Stimulation Mode with a magnet swipe  Clarified the diagnostics active during each mode  Updated Recharge Mode to allow it to operate while in Bootloader Mode  Command latency requirements were removed The IPG will now be shipped from the factory with a full battery.  When charging, the constant-voltage phase will be skipped  Charge rate control updates for wording  Added unpaired MICS communications to allow an unpaired PPC to charge an IPG  Clarified commands for test stimulation and titration stimulation  Added several commands for general testing purposes  Updated Background Impedance Measurement:  Selectable amplitudes are 200uA (default) and 100uA  Pulse width is fixed at 200us and four pulses used to make measurement  Only the channels in the program just used will be checked  “Open” threshold set to 7500W ±500W  Updated Impedance Measurement on Demand  Selectable amplitudes are 500uA (default) or 200uA  Pulse width is fixed at 200us and four pulses used to make measurement  Output Capacitor check was updated to use the same parameters as background impedance measurement, but only a single pulse will be used  The use of a backup temperature sensor was removed  Clarified the difference between system clock checks (MSP430 crystal oscillator and MICS strobe) and stim-related clock checks (pulse guard and stim program period)  Added specs for the different error categories  Added specs for active error handling and prioritization  Removed the brownout fault detection  Simplified the recovery process when Stim  Output Check or Pulse Guard errors occur during stimulation  Removed the fault detection for a faulty stim output channel  Removed the fault detection for too much time spent in constant-voltage recharge  Removed the fault detection when the external charger is delivering unwanted power  Removed the fault detection for MICS and Stim clock errors  Removed factory section from the IPG functional spec to address in lower level design document  Removed ESD (F2730 and child reqs)  Removed Cautery steady state (F88)  Removed induced voltages (f104 and child reqs)  Added 10mT Static Magnetic Field (F8552)  Added Sinusoidal Field Exposure (F8551)  Added EN 45502-2-1 to F2723 reference  Updated X-ray requirement (F85) and added detail to reference  Clarified operation during and after for EMI section  Removed regulatory compliace from F2754, deferring to F8536  Removed F2719 due to redundancy with F84 ("and capable of normal operation")  Added default ERI of 120 months to F7265  Extensive grammar cleanup and wording for testability | 1930 | 9/17/2013 |
| 1.6 | Moved specification from CaliberRM to Cognition Cockpit including extensive updates to formatting and organization of individual requirements to improve traceability  Removed language around setting frequency threshold for switching between active and passive recovery (FRS0547)  Removed brownout detection  Removed functional requirements that involve proving a negative including  FRS0753 “not run checks”  FRS 0839, 0840  Removed clock check FRS0813, FRS0828, FRS1125, FRS1118  Removed requirements around recharge in Bootloader including FRS0833, FRS0844, and updated language in FRS 0819, 0820, 0821, 1220, 1221, 1222  Remove requirement on magnet sensor compatibility with MRI FRS0849  Simplified language on battery disconnect switch  Clarified impedance check number of pulses is fixed at 4 (FRS1015)  Removed basic output check (FRE 1009, 1026, 1056, 1057)  Remove memory check in context of pulse guard failure (mem check on restart stim)  Consolidated language on startup errors (removed frs1107)  FRS 1173 – aligned ultrasound requirement with standards (functional after rather than during and after)  Clarified swipe to reflect timing is not adjustable (FRS1223)  FRS1233 updated to reflect command available during unpaired charging  Removed requirement for inline circuit protection | 2025 | 11/5/2013 |
| 1.7 | Changed amplitude accuracy limits in FRS 0513 and FRS0523 | 2090 | 11/21/13 |

# References

# References

4.1.2 Stimulus Output Electrical Specifications (F2691)

Leakage - 14708-1, 14708-3 Section 16.2

4.1.3.1 Switching between Passive and Active Recovery (F4939)

Frequency thresholds must be programmable because CBC is; changing CBC would invalidate thresholds.

4.7.1 Battery Specifications (F2804)

Reference To MESP 0089 Rechargeable LI-Ion Specification

4.7.7 Charging Rate Control (F8516)

EN 45502-2-2 appendix cc.2 section 17.1 references why this is dependent on time.  42° C was determined to be safe for 30 minutes, and for each degree C multiply by 4.  Thus 40°C should be safe for a minimum of 8 hours.

FC Henriques, Studies of thermal injury. V. The predictability and the significance of thermally induced rate processes leading to irreversible epidermal injury, Arch Pathol 43 (1947), pp. 489–502. 7

4.7.8 Elective Replacement Indicator (F7265)

See ISO 14708-1 19.2.  While the intent seems to read toward primary cells, ERI is included based on projections for overall battery lifetime.

4.8.3 Unpaired MICS Communications (F8515)

The intent behind this requirement is to only allow wakeup via 400 MHz signal when the charging paddle is present.  This is for two reasons:

1) the 400 MHz wakeup is power-hungry, so we wish to limit this to conditions where external power is available.

2) the unpaired communications is used for linking unpaired devices, so it is necessary to have this be an action that is obvious to the user (no unintended pairing).

4.11.1 Defibrillation Compatibility (F89)

specification 20.2 of EN 45502-1:1997

4.11.2 Compatibility with Electrical Cautery Equipment (F86)

EN 45502-2-1:2003 §   21.2

ANSI AAMI PC69 2007 § 6.1

4.11.2.1 Electrocautery Compatibility Under Burst Application (F87)

21.2 of EN 45502-2-1:2003

4.12.2 Static Magnetic Fields (F2723)

ISO 14708-3 §27.103, ANSI/AAMI PC-69 §4.6, §4.7, EN 45502-2-1 §27.6 & 27.7

4.12.3 Magnetic Fields 10 - 30 MHz (F2726)

ISO 14708-3 §27.104.

4.12.4 Electromagnetic Fields in Range 30 MHz - 450 MHz (F2729)

ISO 14708-3 §27.105

4.12.5 Protection from EMF in the Range of 450 MHz to 3 GHz (F100)

ISO 14708-3 §27.106,

ANSI/AAMI PC-69:2007 §4.9

ANSI/AAMI PC-69:2000 §6.

4.13.2 X-Ray Radiation Exposure Requirements (F85)

Estimated exposure during lifetime of IPG is 50 rads (based on 40 diagnostic chest X-rays at 400 mRads per exposure, and 6 minutes of fluoroscopy at 5 rads / minute).  Testing at 150 rads is performed to account for a “3X safety factor”.