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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix F – Electromagnetic Compatibility

F. Appendix F – Electromagnetic Compatibility

This section contains:

F.1. Prior Discussions, Risk Mitigations, and Conclusions

F.1.1. Prior Discussions with FDA on EMC

Electromagnetic compatibility testing has been a topic of multiple previous discussions with FDA, both during our earlier (disapproved) IDE, G110005, and during our Early Feasibility pre-IDE, I111144. These discussions are recapped briefly here for completeness, and serve to support our final scope of testing and methods.

PRIOR DISCUSSIONS ON ELECTROSTATIC DISCHARGE TESTING

Prior discussions with the FDA centered on: 1) the need for ESD testing for the *implanted* components; 2) the methods used to conduct ESD testing for the *implanted* components; and 3) methods used to conduct ESD testing for the *external* components. There was agreement that ESD testing of the implanted components should be conducted based on the rationale that conducting electrodes and cables in the forearm and hand could draw damaging currents to the electronic circuitry, causing a device failure. However, since standards do not specify the ESD exposure ranges for an *implant*, we provided a rationale for basing our methodology on the IEC60601-1-2 recommended tests for both air discharge and contact discharge, using a +/- 8 kV maximum, as these more closely reflect household sources that could be experienced by subjects. In early discussions, FDA suggested we consider a wider test range (+/- 15 kV, or +/- 30 kV); however, following review of our modified protocol, FDA directed us in their pre-IDE response to simply provide a more thorough rationale for our chosen methods and pass/fail criteria (*Question 2c*). These are included in the ESD Testing that appears in *F.2 – Electrostatic Discharge Testing*, below. ESD testing for the *external* components is also provided in that section.

PRIOR DISCUSSIONS ON IMMUNITY, EMISSIONS, AND WIRELESS CO-EXISTENCE

FDA was in agreement that one approach at the Early Feasibility stage is to identify potential sources of EM interference and mitigate their potential risk by controlling or limiting device usage and/or specific environments of use. In particular, FDA expressed concern about susceptibility of power wheelchairs and other things where the user cannot be instructed to avoid the source. There was agreement we should test each subject's system (prior to implanting) with their own wheelchair and consider excluding them from the study if interference existed. We were encouraged to conduct the same types of tests called out in either IEC60601-1-2 or ISO14708-3, but either way to justify the choice of tests, the methods used, and the acceptance criteria. We were encouraged to consider testing for immunity at a level greater than 3 V/m, which was felt to be inadequate. Our proposed scope of testing and methods, described in the sections below, were felt to be acceptable at this stage, but prompted the clarifying issues raised in FDA's pre-IDE response, Questions 2-6. We believe we have addressed these issues in the reports that follow and in our responses in *1.4.2 – Summary of Response to Pre-IDE I111144*:

- Sections F.3.1 and F.3.4 present test results for completed Immunity and Emissions testing.
- Section F.3.2 presents our plan for future testing prior to expanding to a pivotal clinical study.
- Section F.3.3 presents our rationales for tests we do not intend to conduct.

F.1.2. Principles of Wireless Communication Design

The NNP system utilizes two wireless links, as noted in Table F-1.

TABLE F-1: TYPES OF WIRELESS LINKS USED IN THE NNP SYSTEM

TYPE	FREQUENCY	COMMUNICATION BETWEEN	USED FOR
Inductive recharge field	3.5 kHz	Recharge Coil and Power Module	Recharging battery
MedRadio Communication Link	402-405 MHz	Power Module and Control Tower	Programming of implanted components

The following high-level design principles were used during the design of the wireless communication methods for the NNP:

1. **Minimize wireless communication for user functions**. The wireless communication link is used primarily for programming the implanted components in the clinical laboratory, and has only restricted use outside of the lab. For operation of the NNP System outside of the laboratory, it is possible to perform all functional tasks without the Medradio link being active. However, users may use the link in order to obtain the battery charge status, choose an operating mode, or receive operating status feedback. These functions are not time-critical or safety-related.

2. **Minimize use of wireless communication for safety-related functions or time-critical functions.** The NNP does not use wireless communication for any safety-related functions or time-critical functions. In the clinical setting, it is used for programming the implants. The data transmitted over this link can be re-sent if errors are detected. In the presence of significant interference, this process may take a relatively long period of time. If necessary, the programming session could be moved to a different environment offering EMI protection.

3. **Choose communication methods and protocols that permit coexistence with other emitters in the same band**.
   a. **NNP uses the FDA/FCC regulated MedRadio frequency band and communication protocol**. The MedRadio frequency band is *only* authorized for implantable medical devices. Medical devices that use the MedRadio band must follow the FCC protocols for this band. These protocols use a "Listen-Before-Talk (LBT)" criteria. If a nearby medical device is already using a frequency in the MedRadio band, the NNP wireless link will automatically attempt transmission on other MedRadio frequencies (10 channels available). If no open frequency is detected, then it will either be necessary to wait until one or more nearby device stops transmitting or relocate to an area away from the other transmission sources. This feature prevents the NNP System from generating RF that will interfere with other medical devices.
   b. **NNP uses low power transmission from the implanted device (also specified by MedRadio).** The NNP System also implements a session key protocol, which requires the external Control Tower to generate an access

code that is unique for each communication session. This eliminates any possibility of confusion if multiple devices are attempting to communicate at the same time, since the access code is part of the preamble of each subsequent message. At the end of a communication session, both the Control Tower and Power Module discard the access code.

F.1.3. Proposed Risk Mitigations: Screening, Restrictions, Training, and Labeling

As agreed to in our discussions with the FDA, a risk-based approach will be used as we continue to develop and refine the EMC-related aspects of the NNP System. We have a common understanding that this approach is reasonable because:

- The NNP System is not life-supporting or life-sustaining;
- The NNP System is not used for diagnostic purposes;
- The electrical stimulation parameters are limited to safe levels through hardware design;
- Any risk related to conditions where stimulation 1) suddenly stops; 2) stimulates erratically; or 3) maintains stimulation at a constant level, can be mitigated through controls on device use. These conditions may cause the system to fail to provide function, but the resulting stimulation output is safe to the tissue.
- The NNP System has an easy-to-activate Power Off feature that subjects can use if they need to quickly turn off the unit. If that fails to operate, the system also includes a failsafe function that can be activated by placing a strong magnet over the implanted components, immediately disconnecting power from the rest of the system and stopping all activity.

As agreed to in our discussions with FDA, a number of specific risk mitigations will be used at the Early Feasibility stage, as noted in Table F-2, below.

TABLE F-2. SUMMARY OF RISK MITIGATIONS FOR EMC: SCREENING, TRAINING, AND LABELING

SCREENING	Subjects' wheelchairs will be tested for compatibility with the system prior to being enrolled in the study. Incompatibilities will be handled on a case-by-case basis and may form the basis for excluding a subject from the study.
	Study subjects will be excluded if they have an "active implantable medical device with unknown or untested interaction with the NNP implant." We do not believe evidence supports a contraindication statement in the labeling at this time. Results of the clinical study and subsequent EM characterization will provide evidence necessary to support any contraindications for the system.
USER RESTRICTIONS	Based on the results of our current testing, it does not appear necessary to restrict the environment of use for subjects. Nevertheless, training and consent documents will convey the need to potentially do this.
TRAINING	Training for both subjects and clinical staff will emphasize effects of sources of EMI, how to recognize sources, how to recognize potential interference, and what to do in the event of EM interference.
	Subjects will be educated through direct training on how to identify a failed Control Tower. Failed Control Tower systems will be replaced as needed for each subject.
	Training for both subjects and clinical investigators / staff will include review of contraindications, warnings, precautions, and instructions.
LABELING	Warnings and precautions have been added to the Patient Manual to address concerns about MRI exposure, other electrical stimulation systems, ultrasound, lithotripsy, x-rays, mammograms, and diathermy.
	The section entitled, "When to Call Us" now contains a statement, "If you experience

	any unusual performance of the system that may be caused by proximity to electromagnetic sources. Any unusual performance of the system should be reported so that we can trouble-shoot possible causes."
	The package label for implanted components will indicate that the device is MR Unsafe and will include appropriate markings to indicate MR Unsafe.
	The Patient Manual has been updated to include a warning concerning exposure to diathermy. Our testing supports the safe use of a cell phone with the NNP and this has been noted in the labeling.
	The Patient Manual has been updated to include a warning about pacemaker magnets.
	The Patient Manual has been updated to include a caution about proximity to security systems such as metal detectors and anti-theft systems.

F.1.4. Conclusions

Based on our prior discussions with FDA, it is understood that we do not intend to make modifications to our system to address EMC-related issues *prior* to embarking on the Early Feasibility study. Based on our Risk Analysis, Device Evaluation Strategy and results of EMC characterization conducted to date, we conclude the following:

- The potential risks associated with EM sources are of low severity and likelihood to begin with since the NNP system is not life-supporting or life-sustaining;
- The design of the NNP system mitigates many of the hazards due to electrical stimulation levels being limited to safe levels through hardware limits;
- The NNP failsafe function further prevents aberrant system performance from causing harm to subjects;
- The NNP responses to EM sources have been sufficiently characterized in our test protocol with results indicating no safety-related outcomes;
    - The external and internal components demonstrate adequate defense against electrostatic discharge and are safe to begin use in an Early Feasibility IDE study.
    - The NNP System can be safely used in the presence of a wide variety of emitters without degradation of performance.
    - The NNP System complies with Class B (Industrial) limits on emissions, but is a very weak emitter in a narrow range of Class A (Residential) frequencies.
    - The NNP System can be safely used with cell phones, Wifi, and cordless phones without interference.
- Further mitigations in the form of screening criteria, user training, and labeling can be used to reduce risks to subjects in the Early Feasibility IDE; and
- The NNP system is sufficiently safe to begin use, without further modification, in a limited human feasibility study.

F.2. Electrostatic Discharge Testing

F.2.1. External Components ESD Test

PURPOSE

ESD testing was performed on the Control Tower and charger as described in IEC 60601-1-2:2001 (up to +/- 6KV contact discharge and +/- 8KV air discharge (Test Level 3)). We do not claim compliance with this standard in the Early Feasibility stage. The information from this test will be used to identify any potential failure modes in the external components. External component failure will require replacement of the component, but is not a safety concern for the patient.

METHODS

The equipment under test (EUT) consisted of the Control Tower, Recharge Coil, Remote Display, and AC Power Adapter. The test was conducted on a non-conducting table with metal legs. A horizontal conducting plane covered with an insulating support was placed under the EUT. A Haefley PESD1600 ESD generator was used to deliver both air discharges and contact discharges using the appropriate electrodes. Ten discharges of each voltage for each polarity were delivered with a minimum of 1 second between each discharge. The EUT was equalized with the ground plane through two 470K resistors connected in series after each discharge. Air discharges were applied to various accessible parts including pushbuttons, displays, enclosures, and connectors. Contact discharges were applied to conductive accessible parts. The EUT was tested in both a power off and functional mode (Power Module battery recharge). Compliance was checked following the methods described in 60601-1-2 36.202.1 j, after each discharge. Upon completion of the ESD testing, the EUT was tested for proper function.

RESULTS

TABLE F-3. EXTERNAL COMPONENTS ESD TEST SUMMARY.

ITEM	MODE	VOLTAGE	POLARITY	EUT	RESULT
	Air Discharge				
1		2KV	+	Off	**PASS**
2		2KV	+	On	**PASS**
3		2KV	-	Off	**PASS**
4		2KV	-	On	**PASS**
5		4KV	+	Off	**PASS**
6		4KV	+	On	**PASS**
7		4KV	-	Off	**PASS**
8		4KV	-	On	**PASS**
9		8KV	+	Off	**PASS**
10		8KV	+	On	**PASS**
11		8KV	-	Off	**PASS**
12		8KV	-	On	**PASS**
	Contact Discharge				
1		2KV	+	Off	**PASS**
2		2KV	+	On	**PASS**
3		2KV	-	Off	**PASS**
4		2KV	-	On	**PASS**

5		4KV	+	Off	**PASS**
6		4KV	+	On	**PASS**
7		4KV	-	Off	**PASS**
8		4KV	-	On	**PASS**
9		6KV	+	Off	**PASS**
10		6KV	+	On	**PASS**
11		6KV	-	Off	**PASS**
12		6KV	-	On	**PASS**

CONCLUSIONS
The external components demonstrate adequate defense against electrostatic discharge and are safe enough to begin use in an Early Feasibility IDE study.

F.2.2. Implantable Components ESD Test

METHODS
The test was conducted in a saline phantom, analogous to the anatomical configuration of the upper extremity and trunk. The NNP System components were positioned within the saline torso as they would be situated *in vivo*. Electrostatic discharges were applied to this system utilizing an ESD delivery gun (Haefley PESD1600). Both air and contact ESD discharges were applied to the "hand" region of the saline bath.

Ten air discharges were done at each polarity, + and -, for the following voltage test levels: 2KV, 4KV, 8KV and 15KV. Ten contact discharges were applied at each polarity, + and -, for the following voltage test levels: 2KV, 4KV, 6KV and 8KV. The saline phantom was tested as "Ungrounded Table-top Equipment" according to IEC61000-4-2:2008 test level 4 with the following minor variations:

1. Because the phantom itself included an insulating layer, the insulating layer specified between the system under test and the horizontal coupling plane was omitted.
2. The copper horizontal coupling plane used beneath the System Under Test was thinner than the 0.25mm specified in the requirements.
3. The copper horizontal coupling plane was under the system but did not extend the specified 0.1m beyond the perimeter in all directions.
4. The table on which the test was performed had painted metal legs and a non-conductive tabletop.

The function of the implanted components following this delivery was verified following a standard protocol. The ESD test is performed with the implant devices powered up and operating, and then repeated with the entire system powered off.

ACCEPTANCE CRITERIA
The ESD test is considered "PASSED" if the unit under test successfully demonstrates functional stimulation and recording ability at the conclusion of the ESD testing. Units that don't demonstrate functional stimulation and/or recording ability will be considered FAILED. Annotations will be made for any FAILED test that results in any implanted

component exhibiting loss of operation consistent with what would require surgical repair or replacement.

RESULTS

TABLE F-4. INTERNAL COMPONENTS ESD TEST SUMMARY.

ITEM	MODE	VOLTAGE	POLARITY	EUT	RESULT
	Air Discharge				
1		2KV	+	Off	**PASS**
2		2KV	+	On	**PASS**
3		2KV	-	Off	**PASS**
4		2KV	-	On	**PASS**
5		4KV	+	Off	**PASS**
6		4KV	+	On	**PASS**
7		4KV	-	Off	**PASS**
8		4KV	-	On	**PASS**
9		8KV	+	Off	**PASS**
10		8KV	+	On	**PASS**
11		8KV	-	Off	**PASS**
12		8KV	-	On	**PASS**
13		15KV	+	Off	**PASS**
14		15KV	+	On	**PASS**
15		15KV	-	Off	**PASS**
16		15KV	-	On	**PASS**
	Contact Discharge				
1		2KV	+	Off	**PASS**
2		2KV	+	On	**PASS**
3		2KV	-	Off	**PASS**
4		2KV	-	On	**PASS**
5		4KV	+	Off	**PASS**
6		4KV	+	On	**PASS**
7		4KV	-	Off	**PASS**
8		4KV	-	On	**PASS**
9		6KV	+	Off	**PASS**
10		6KV	+	On	**PASS**
11		6KV	-	Off	**PASS**
12		6KV	-	On	**PASS**
13		8KV	+	Off	**PASS**
14		8KV	+	On	**PASS**
15		8KV	-	Off	**PASS**
16		8KV	-	On	**PASS**

CONCLUSIONS

The internal components demonstrate adequate defense against electrostatic discharge and are safe enough to begin use in an Early Feasibility IDE study.

F.3. Immunity and Emissions Testing Methods and Assumptions

Table F-5, below, summarizes the scope of components evaluated in the EMC testing.

TABLE F-5. NNP SYSTEM COMPONENTS EVALUATED DURING IMMUNITY AND EMISSIONS TESTS

	CHARGING MODE	NORMAL MODE (IMPLANT ONLY)
IMMUNITY *Are the following components disrupted by RF interference?*	• Radio • Power Module Circuitry (thermistor, A/D) • Control Tower Circuitry (thermistor)	• FESCAN • Power Module Circuitry • Remote Module Circuitry • Remote Sensing analog
EMISSIONS *How much are the following components contributing to emissions?*	• Coil • Radio • Control Tower Circuitry • Power Module Circuitry	• FESCAN • Power Module Circuitry • Remote Module Circuitry • Stimulus

Figure F-1, below, shows the NNP System setup used in the test, representing the full set of components necessary to provide both hand grasp and trunk stability. Implantable components were placed in a room-temperature saline "phantom" representing a human torso and arm. External components were place in locations typical of the clinical scenario.

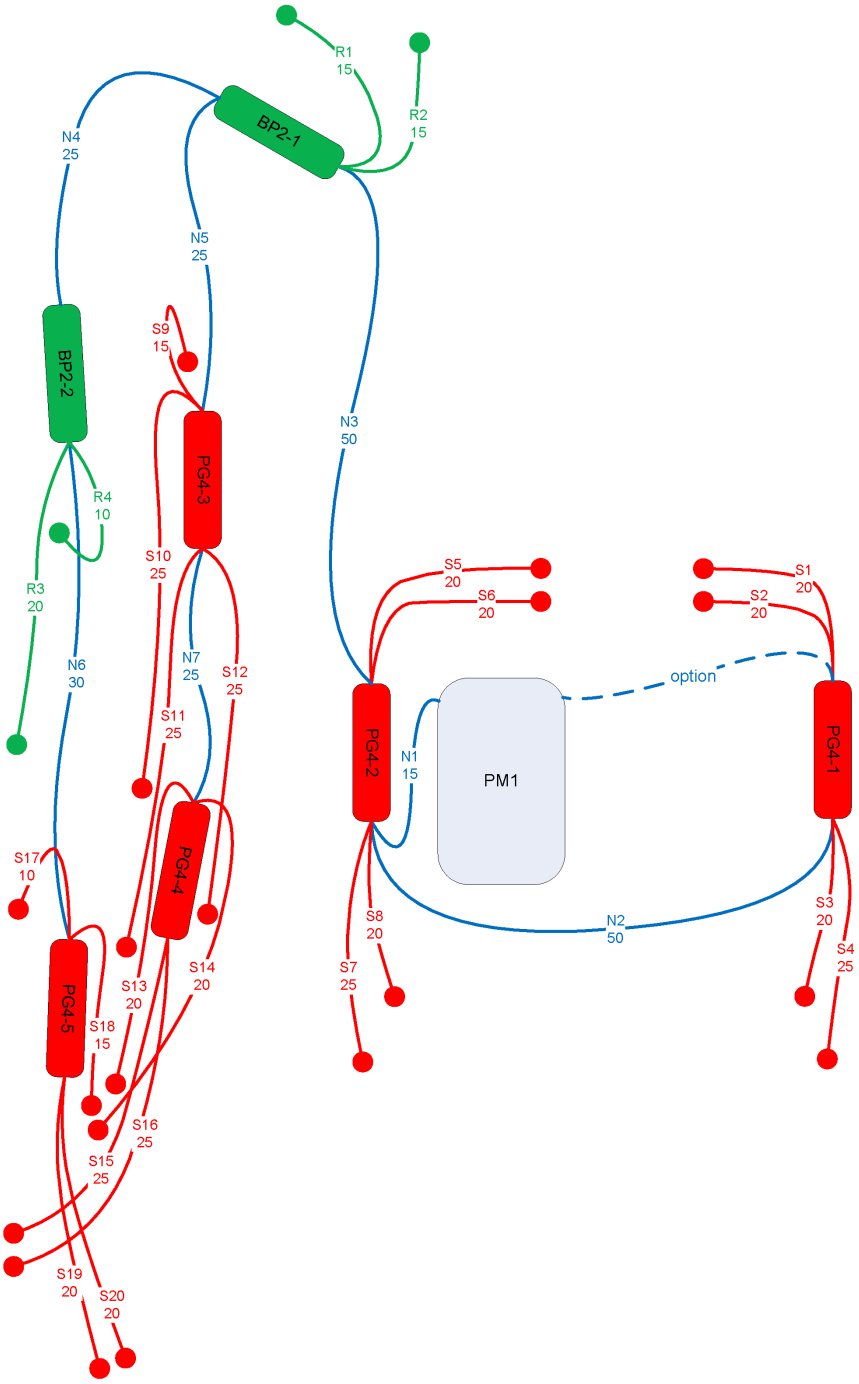

Figure F- 1. NNP implanted components used in EMC testing. Components were placed in a saline phantom representing the torso and arm.

F.3.1. Immunity Testing – Radiated EM Fields

(The complete test report from F2 Labs is presented in Section F.4, below.)

This test follows the methods described in ISO 14708-3 section 27, criterion A. However, please note that we are not claiming conformance with this standard at the EFS IDE stage. Immunity testing was conducted in both "Normal Mode" and "Charging Mode". Normal Mode included all the implanted components needed for a full hand and trunk system running in high-speed myoelectric recording mode while simultaneously stimulating at maximum levels. Charging Mode evaluated the Power Module (implant) running in charging mode with a maximum possible requested charge rate of 100mA per battery, while communicating with external system components. These conditions reflected a sufficiently challenging clinical scenario in terms of both hardware used in the configured set-up and functions evaluated.

TABLE F-6. SUMMARY OF RESULTS FROM IMMUNITY TESTING

NORMAL MODE	CHARGING MODE	NAME	IEC 60601-1-2 REQUIREMENT	80 MHZ TO 1 GHZ	1 – 2.5 GHZ
Implantable components only	Implantable components communicating with external components	Electric fields, alternating	ESSENTIAL PERFORMANCE is maintained. (See details in Table F-7, below)	3 V/m (4 positions, horizontal and vertical antenna) **PASSED**	3 V/m (2 positions, horizontal and vertical antenna) **PASSED**
				18 V/m (1 position: horizontal and vertical antenna) **PASSED**	

TABLE F-7. EVALUATION OF ESSENTIAL PERFORMANCE, PER IEC 60601-1-2

DEGRADATIONS: *Under the test conditions specified in 36.202, the EQUIPMENT or SYSTEM shall be able to provide the ESSENTIAL PERFORMANCE and remain safe. The following DEGRADATIONS associated with ESSENTIAL PERFORMANCE and safety shall **not** be allowed:*	
COMPLIANCE CRITERIA	**DEGRADATIONS OBSERVED**
Component failures	None
Reset to factory defaults	None
Change in operating mode	None
False alarms	None
Cessation / interruption of any intended operation, even if accompanied by an alarm	None

Error of a displayed numerical value sufficiently large to affect diagnosis or treatment	None
Noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals.	None
Artifact or distortion in an image in which the artifact is indistinguishable from physiologically-produced	None
Signals or the distortion interferes with interpretation of physiologically-produced signals	None
Failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm	None

OBSERVATIONS: *The equipment or system may exhibit degradation of performance (e.g., deviation from manufacturer's specifications) that does not affect essential performance or safety.*

OBSERVED PERFORMANCE	**RATIONALE**
Radio disruption: Some radio telemetry packets were dropped.	Dropped radio packets do not affect the safety of the system, or cause a change in the mode of operation of the NNPS. The system can be left running in any mode and will either shut itself down after its batteries drop below a critical level or can be shut down via the Failsafe Function at any time. The observed effects were transient and did not result in permanent alteration in performance requiring revision or replacement of the implanted components of the system.

CONCLUSIONS

- The NNP System can be safely used in the presence of a wide variety of emitters without degradation of performance.

F.3.2. Planned Evaluations of Immunity

Following discussions with FDA, and based on our Risk Analysis and Device Evaluation Strategy, our plans for further Immunity testing will include the following evaluations, which will be completed prior to expanding to a pivotal clinical trial:

CONDUCTED DISTURBANCES INDUCED BY RF FIELDS (EN 60601-1-2, 6.2.6)
The Control Tower is the only line-powered device utilized with the NNP System. An EN 60601-1-2 approved Line Power Adapter will be utilized with the Control Tower. Conducted disturbances through the Control Tower will be evaluated per EN 60601-1-2 and IEC 61000-4-6:2008, tested on the line powered programming configuration (Control Tower & Laptop PC) as well as the Control Tower alone (home use configuration). The results will be used to evaluate the potential for disruption and characteristics of disruption, and may form the basis for modifications to the User's Manual or Investigational Plan.

LINE POWER MAGNETIC FIELDS (EN 60601-1-2, 6.2.8)
The effect of dynamic magnetic fields will be evaluated for both the implantable and external components, per EN 60601-1-2 using 50Hz / 60Hz magnetic fields at 3 A/m. The implantable system will also be evaluated in HF magnetic fields to the A-line limits of ISO 14708-3:2008. Results will be used to evaluate the potential for disruption and characteristics of disruption, and may form the basis for modifications to the User's Manual or Investigational Plan. Controls may be placed on device usage as necessary, based on the results of this evaluation.

F.3.3. Waived Evaluations of Immunity

Following discussions with FDA, and based on our Risk Analysis and Device Evaluation Strategy, the following aspects of Immunity will not be characterized in further testing, with rationales provided:

ELECTRICALLY FAST TRANSIENTS & BURSTS (EN 60601-1-2, 6.2.4)
The Control Tower is the only line-powered device utilized with the NNP System. An EN 60601-1-2 approved Line Power Adapter will be utilized with the Control Tower, and no further characterization will be performed.

SURGES (EN 60601-1-2, 6.2.5)
The Control Tower is the only line-powered device utilized with the NNP System. An EN 60601-1-2 approved Line Power Adapter will be utilized with the Control Tower, and no further testing will be performed.

VOLTAGE DIPS (EN 60601-1-2, 6.2.7)
The Control Tower is the only line-powered device utilized with the NNP System. An EN 60601-1-2 approved Line Power Adapter will be utilized with the Control Tower, and no further testing will be performed.

F.3.4. Emissions Testing

(The complete test report from F2 Labs is presented in Section F.4, below.)

TABLE F-8. SUMMARY OF RESULTS FROM EMISSIONS TESTING

NORMAL MODE	CHARGING MODE	NAME	47 CFR 15.109 REQUIREMENT	CLASS A (RESIDENTIAL) LIMIT	CLASS B (INDUSTRIAL) LIMIT
Implantable components only	Implantable components communicating with external components	Radiated fields	Per 47CFR15.109 (g), the simple IEC CISPR 22 section 6.1 emissions limits can be used by Class B (residential) unintentional radiators at 10 meters.	**EXCEEDS LIMIT** Exceeds limits in both modes. Control Tower exceeded limit between 150-400 MHz. Implant exceeds limit between 30-50 MHz. (See Rationale, below)	**PASSED**

RATIONALE

The NNP did not comply with FCC 47CFR15.109 emissions limits for Class A (Residential) devices but the system did comply with the Class B (Industrial) device limits. The system was out of compliance in 2 separate bands: the 30 MHz to 50 MHz band (Active Implantable only) and the 150 MHz to 400 MHz band (External charging unit). Even so, the magnitudes of the device's spurious emissions are extremely low. The highest peak measured was 43.5 dBμV/m (or 150 μV/m). To put this in perspective, a typical radio receiver needs to have about a 10,000 μV/m radio signal in order to pick up a station well (Giordano, 2012). The strongest spurious emission measured from the NNP corresponds to an electric field strength about 100 times smaller than this signal strength. Therefore, the risk of any interference to nearby devices is very small. Additionally, the emissions occur in bands well outside of Cellular, Wifi, and most cordless phones thus negating the possibility of interference was patient communication equipment.

CONCLUSIONS

- The NNP System complies with Class B (Industrial) limits on emissions, but is a very weak emitter in a narrow range of Class A (Residential) frequencies.
- The NNP System can be safely used with cell phones, Wifi, and cordless phones without interference.

F.4. Immunity and Emissions Test Report from F2 Labs

F2 Labs
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Middlefield, Ohio 44062
United States of America
www.f2labs.com

EMC TEST REPORT

Manufacturer:	**Case Western Reserve University** **10900 Euclid Avenue** **Cleveland, Ohio 44106** **United States of America**
Product:	**Networked Neural Prosthetic System**
Model:	**NNPS**
Testing Commenced:	**Sept. 17, 2014**
Testing Ended:	**Sept. 18, 2014**
Summary of Test Results:	**Page 4**

Standards:

- **IEC 60601-1-2:2007 Third Edition, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests**
  - **CISPR 11:2009, inc. A1:2010 -** Limits and methods of measurement of radio disturbance, Characteristics of industrial, scientific and medical radio frequency equipment
  - **IEC 61000-4-3:2010** - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 3: Radiated, radio-frequency, electromagnetic field immunity test
- **ISO 14708-3:2008 - Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators**

Evaluation Conducted by: _____

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GENERAL REPORT SUMMARY

This electromagnetic emission test report was generated by F2 Labs. The test report is based on testing performed by F2 Labs personnel according to the measurement procedures described in the test specifications given below and in the Test Procedures section of this report.

SECTION	TEST	RESULTS
9	Radiated Immunity	Complies
10	Radiated Emissions	Does Not Comply

** Complies per client declaration that loss of radio communications is not considered a degradation and does not affect the product's essential performance.*

Note: Pass/Fail criteria are based upon the following condition: Where the results are compared to published test standard or manufacturer specified limits, the PASS or FAIL opinion is considered without applying the laboratory stated measurement uncertainty.

Reports noted as a revision replace all previously issued reports and/or antecedent report revisions issued under this job number.

1.0 ADMINISTRATIVE DATA

1.1 Management of Test Sample

The test sample was inventoried at the F2 Labs facility and returned to Case Western Reserve University, according to the agreement between F2 Labs and the Client.

1.2 Abbreviations and Acronyms

The following abbreviations and acronyms may be used in this document.

AM	Amplitude Modulation
BCI	Bulk Current Injection
CDN	Coupling/Decoupling Network
EFT	Electrical Fast Transients
EMC	Electromagnetic Compatibility
EMIC	Electromagnetic Injection Clamp
EN	European Norm
ESD	Electrostatic Discharge
EUT	Equipment Under Test
GRP	Ground Reference Plane
HCP	Horizontal Coupling Plane
IEC	International Electrotechnical Commission
kHz	kiloHertz
LISN	Line Impedance Stabilization Network
MHz	MegaHertz
OATS	Open Area Test Site
RF	Radio Frequency
VCP	Vertical Coupling Plane

1.3 Document History

Document Number	Description	Issue Date	Approved By
F2Q6320-01E	First Issue	Sept. 24, 2014	K. Littell
F2Q6320-01E Rev. 1	Revision of Radiated Immunity results summary and various minor revisions based on client feedback.	Oct. 14, 2014	K. Littell

2.0 PERFORMANCE CRITERIA

SPECIFICATION	MINIMUM PERFORMANCE CRITERION
IEC 61000-4-3	IEC 60601-1-2:2007, page 87, Sec. 6.2.1.10

Under the test conditions specified in 6.2.1.10, the *equipment or system* shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and safety shall not be allowed:

- Component failures;
- Changes in programmable parameters;
- Reset to factory defaults (manufacturer's presets);
- Change of operating mode;
- False alarms;
- Cessation of interruption of any intended operation, even if accompanied by an alarm;
- Initiation of any unintended operation, included unintended or uncontrolled motion, even if accompanied by an alarm;
- Error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- Noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;
- Artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- Failure of automatic diagnosis or treatment *equipment and systems* to diagnose or treat, even if accompanied by an alarm.

For *equipment and systems* with multiple functions, the criteria apply to each function, parameter and channel.

The equipment or system may exhibit degradation of performance (e.g., deviation from manufacturer's specifications) that does not affect essential performance or safety.

3.0 MEASUREMENT OF UNCERTAINTY BUDGETS

The uncertainty in EMC measurements arises from several factors which affect the results, some associated with environmental conditions in the measurement room, the test equipment being used and the measurement techniques adopted.

The measurement uncertainty budgets detailed below are calculated from the test and calibration data.

MEASUREMENT	EXPANDED UNCERTAINTY
Radiated Immunity	2.12dB
Radiated Emissions	5.353dB

This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

4.0 LISTS OF EUT, ACCESSORIES AND TEST EQUIPMENT

4.1 Equipment Under Test (EUT):

Device	Manufacturer	Model Number	Serial Number
Networked Neural Prosthetic System	Case Western Reserve University	NNPS	None Spec.
consisting of:			
Control Tower	Case Western Reserve University	None Spec.	None Spec.
Remote BGX Display	Case Western Reserve University	None Spec.	None Spec.
Implant	Case Western Reserve University	None Spec.	None Spec.

4.2 Accessories (Support Equipment):

Device	Manufacturer	Model Number	Serial Number
Laptop	Cretac	P470	R9439P0067
Laptop Supply	Delta Electronics	ADD-905B BB	Y1J0910000325
Mouse	Dell	None Spec.	None Spec.

4.3 Cables:

Cable Function	Length	Shielded (Yes/No)
PC: AC Mains	>3m	No
Coax	>3m	Yes
Mouse: USB	<3m	Yes
Charger: AC Mains	>3m	No
I/O	<3m	No

5.0 MODE OF OPERATION

EUT was set up in a normal operating mode, with device sending data to a PC.

6.0 METHOD OF MONITORING

Monitored EUT visually by viewing data on the laptop.

7.0 IMMUNITY PERFORMANCE CRITERIA

The following shall constitute susceptibility:

- If the EUT shuts down;
- If the EUT stops sending data to the PC.

8.0 REQUIRED MODIFICATIONS

No modifications were made to the EUT.

9.0 RADIATED IMMUNITY TEST

9.1 Radiated Immunity Test Procedure

The Equipment Under Test (EUT) was placed in a semi-anechoic chamber on a 0.8-meter high non-conductive table. A broadband antenna was placed 1.8 meters from the EUT and was used to radiate RF energy at the EUT in both horizontal and vertical polarities.

The RF energy consisted of a signal that was stepped at 1% increments through the frequency range of 80 MHz to 1 GHz, and 1 GHz to 2.5 GHz, at a rate slower than the reaction time of the EUT. The signal was 80% AM modulated with a 1 kHz sine wave and had a minimum calibrated field strength of 3.0 volts/meter at the surface of the EUT. The EUT was exposed to the RF energy on four different surfaces (front, rear, left and right sides).

The test setup confirmed to figure 2 of IEC 61000-4-3.

Test Equipment Used:

Equipment Type	Asset Number	Manufacturer	Model	Serial Number	Calibration Due Date
Shield Room	0175	Ray Proof	N/A	11645	Verified
Temp/Hum. Recorder	CL137	Extech	RH520	CH16992	May 5, 2015
Antenna 1-Chamber	0142	ETS/EMCO	3142B	9811-1330	Verified
Antenna, Horn	0138	ARA	DWG-118/A	1109	Verified
Amplifier	0171	Instruments for Industry	SMX 100	2158-1096	Verified
Amplifier	0185	Ophir	5151F	1001	Verified
Power Meter; Power Sensor	CL148	Agilent Technologies	E4418B; E9300B	MY41294473; MY41496326	May 7, 2015
Signal Generator	CL060	Rohde & Schwarz	SMIQ06B	1125.5555.06/ 834606/025	Apr. 30, 2015
Software:	Tile Version 1.0		Software Verified: Sept. 17, 2014		

9.2 Radiated Immunity Test Data Sheet

Test Date:	Sept. 17, 2014	**Test Engineer:**	M. Toth
Standard(s):	IEC 60601-1-2:2007; ISO 14708-3:2008	**Air Temperature:**	22.6°C
Minimum Performance Criteria:	IEC 60601-1-2:2007, page 87, Sec. 6.2.1.10	**Relative Humidity:**	47%

1% increments, 1.5 sec dwell.
80 MHz to 1000 MHz
Implant Only
Stimulation on 3 Ch 1
High Speed MES

Patient, Antenna Orientation	Frequency Range (MHz)	Minimum Calibrated RF Field Strength	Achieved Criterion
Left Side, Vertical	80 to 106.7	3.0 V/m	Radio Disruption
Left Side, Vertical	106.7 to 128.9	3.0 V/m	Radio Disruption
Left Side, Vertical	134	3.0 V/m	Radio Disruption
Left Side, Vertical	203 to 207	3.0 V/m	Radio Disruption
Left Side, Vertical	234 to 241	3.0 V/m	Radio Disruption
Left Side, Vertical	80 to 1000	3.0 V/m	Radio Disruption
Left Side, Horizontal	111 to 114	3.0 V/m	Radio Disruption
Left Side, Horizontal	160 to 167	3.0 V/m	Radio Disruption
Left Side, Horizontal	190-218	3.0 V/m	Radio Disruption
Left Side, Horizontal	225-239	3.0 V/m	Radio Disruption
Left Side, Horizontal (Rev. 2)	190 to 198	3.0 V/m (w/foam)	Radio Disruption
Left Side, Horizontal (Rev. 2)	203 to 218	3.0 V/m (w/foam)	Radio Disruption
Patient Foot, Horizontal	177 to 195	3.0 V/m	Radio Disruption
Patient Foot, Horizontal	201 to 217	3.0 V/m	Radio Disruption
Patient Foot, Horizontal	230 to 240	3.0 V/m	Radio Disruption
Patient Foot, Vertical	80 to 87	3.0 V/m	Radio Disruption
Patient Foot, Vertical	91 to 99	3.0 V/m	Radio Disruption
Patient Foot, Vertical	103 to 114	3.0 V/m	Radio Disruption
Patient Foot, Vertical	130 to 143	3.0 V/m	Radio Disruption
Patient Foot, Vertical	148 to 167	3.0 V/m	Radio Disruption
Patient Foot, Vertical	176 to 288	3.0 V/m	Radio Disruption

Patient, Antenna Orientation	Frequency Range (MHz)	Minimum Calibrated RF Field Strength	Achieved Criterion
Right Side, Vertical	80.6 to 84	3.0 V/m	Radio Disruption
Right Side, Vertical	85 to 91	3.0 V/m	Radio Disruption
Right Side, Vertical	95 to 288	3.0 V/m	Radio Disruption
Right Side, Vertical	318 to 331	3.0 V/m	Radio Disruption
Right Side, Horizontal	111 to 114	3.0 V/m	Radio Disruption
Right Side, Horizontal	116 to 121	3.0 V/m	Radio Disruption
Right Side, Horizontal	162 to 167	3.0 V/m	Radio Disruption
Right Side, Horizontal	186 to 248	3.0 V/m	Radio Disruption
Right Side, Horizontal	261 to 280	3.0 V/m	Radio Disruption
Patient Head, Horizontal	101 to 104	3.0 V/m	Radio Disruption
Patient Head, Horizontal	111 to 114	3.0 V/m	Radio Disruption
Patient Head, Horizontal	201 to 204	3.0 V/m	Radio Disruption
Patient Head, Vertical	8 to 84	3.0 V/m	Radio Disruption
Patient Head, Vertical	106 to 138	3.0 V/m	Radio Disruption
Patient Head, Vertical	203 to 210	3.0 V/m	Radio Disruption
Patient Head, Vertical	230 to 246	3.0 V/m	Radio Disruption

Implant Only, RF Absorbers

Patient, Antenna Orientation	Frequency Range (MHz)	Minimum Calibrated RF Field Strength	Achieved Criterion
Left Side, Horizontal	182	18.0 V/m	Radio Disruption
Left Side, Horizontal	195 to 210	18.0 V/m	Radio Disruption
Left Side, Vertical	93 to 125	18.0 V/m	Radio Disruption
Left Side, Vertical	134 to 138	18.0 V/m	Radio Disruption
Left Side, Vertical	201 to 209	18.0 V/m	Radio Disruption

Charging Mode

Patient Head, 3V/m, Vertical
9 minutes

Patient Head, 3V/m, Horizontal
Temp 28.3
Time: 13.37

Patient Orientation	Antenna Orientation	Temperature	Time	VREC
Right Side	Horizontal	25.8*	13:47	23.7
Right Side	Horizontal	28.1	13:54	23.5
Right Side	Vertical	28.2	13:54	23.3
Right Side	Vertical	28.4	13:57	23.4
Foot	Vertical	22.5	14:03	22.5
Foot	Horizontal	28.2	14:10	23.0
Left Side	Horizontal	24.8	14:19	22.5
Left Side	Vertical	24.8	14:26	22.0
Left Side	Vertical	28.4	14:26	22.0

**Saline movement.*

Patient Head, 18V/m

Patient Orientation	Antenna Orientation	Temperature	Time	VREC
Left Side	Vertical	28.6	N/A	24.0
Left Side	X until 154 MHz	N/A	N/A	N/A
Left Side	220 MHz to 264	N/A	14:40	N/A
Left Side	N/A	28.1	14:42	24.5
Left Side	Horizontal	28.4	14:44	24.3

Patient Head, 3V/m
Discharge Mode

Patient Orientation	Antenna Orientation	Temperature	Time	VREC	Comments
Left Side	H	N/A	8:45	N/A	No Disruption
Left Side	V	N/A	N/A	N/A	No Disruption
Head	V	N/A	N/A	N/A	No Disruption
Head	H	N/A	N/A	N/A	No Disruption

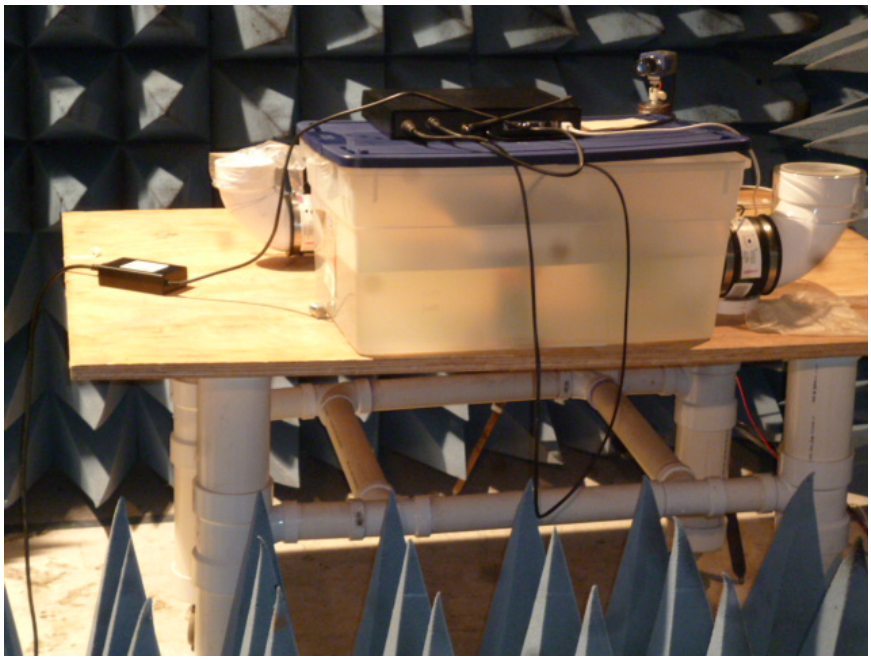
Patient Head, 3V/m
Charging Mode
Run with long USB cable.

Patient Orientation	Antenna Orientation	Temperature	Time	VREC	Comments
Head	H	22.2	9:25	20.5	No Disruption
Left	H	21.7	N/A	22.2	No Disruption
Left	V	24.8	N/A	22.5	No Disruption
Left	V	27.0	9:52	22.4	No Disruption

9.3 Photograph(s) of the Radiated Immunity Test Setup

Front View

Rear View



Right Side View

Left Side View

10.0 RADIATED EMISSIONS TEST

10.1 Radiated Emissions Test Procedure

The EUT was initially placed in a semi-anechoic chamber, and wide band characterization measurements were performed to determine at which frequencies significant emissions occurred.

The equipment was installed on a 0.8-meter high non-conductive turntable on an Open Area Test Site (OATS), as described in CISPR 11. A receiving antenna was located 10.0 meters from the edge of the Equipment under Test (EUT). The antenna was attached to an antenna mast that allowed the antenna height to be adjusted from 1.0 to 4.0 meters above the ground plane.

The equipment was then fully exercised with all cabling attached to the EUT. While the equipment was energized, the receiving antenna was scanned from 1.0 meter to 4.0 meters in both vertical and horizontal polarities while the turntable was adjusted 360 degrees to determine the maximum field strength. During the test, frequencies identified as being generated by the EUT in the frequency range of 30 MHz to 1000 MHz were measured. The highest levels were recorded along with antenna polarity. These levels were then compared to the Class B limits specified in CISPR 11.

Test Equipment Used:

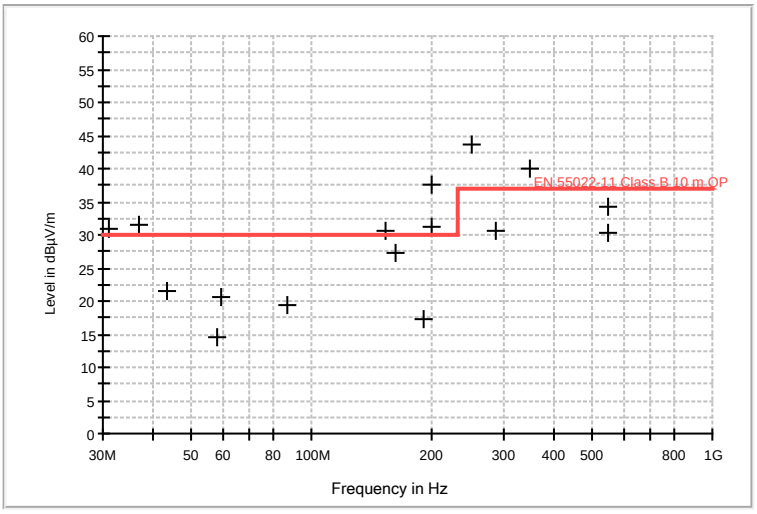
Equipment Type	Asset Number	Manufacturer	Model	Serial Number	Calibration Due Date
Shield Room	0175	Ray Proof	N/A	11645	Verified
Temp/Hum. Recorder	CL137	Extech	RH520	CH16992	May 5, 2015
OATS-10m	CL017	Compliance Labs	N/A	001	Dec. 13, 2014
Spectrum Analyzer	CL138	Agilent Technologies	E4407B	US41192779	Oct. 29, 2014
Receiver	CL151	Rohde & Schwarz	ESU40	100319	Oct. 30, 2014
Antenna 1-Chamber	0142	ETS/EMCO	3142B	9811-1330	Verified
Antenna 2-OATS	0105	Sunol Sciences	JB1	A101101	May 7, 2015
Pre-Amplifier	CL045	Hewlett-Packard	8447D	2944A08445	Nov. 15, 2015
Software:	Tile Version 1.0		Software Verified: Sept. 17, 2014		
Software:	EMC 32, Version 5.20.2		Software Verified: Sept. 17, 2014		

10.2 Radiated Emissions Test Data Sheet

Test Date:	Sept. 17, 2014	**Test Engineer:**	M. Toth
Standard:	CISPR 11:2009, inc. A1:2010	**Air Temperature:**	18.9°C
Limit:	Class B	**Relative Humidity:**	68%
Distance:	10.0 meters		

Frequency (MHz)	Antenna Polarization	Reading (dBµV)	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
31.000000	V	10.8	20.2	31.0	30.0	1.0
37.130000	V	15.9	15.6	31.5	30.0	1.5
43.640000	V	9.8	11.6	21.4	30.0	-8.6
57.710000	H	5.6	9.0	14.6	30.0	-15.4
59.080000	V	11.6	9.1	20.7	30.0	-9.3
86.810000	V	9.5	9.8	19.3	30.0	-10.7
152.130000	H	16.2	14.5	30.7	30.0	0.7
161.180000	V	12.9	14.5	27.4	30.0	-2.6
190.570000	H	3.2	14.2	17.4	30.0	-12.6
199.980000	V	21.8	15.7	37.5	30.0	7.5
199.990000	H	16.0	15.2	31.2	30.0	1.2
250.000000	H	29.0	14.5	43.5	37.0	6.5
287.980000	H	14.0	16.5	30.5	37.0	-6.5
350.000000	V	21.6	18.3	39.9	37.0	2.9
550.00	H	0.00	22.60	22.6	37.0	-30
550.00	V	0.00	23.20	23.2	37.0	-30

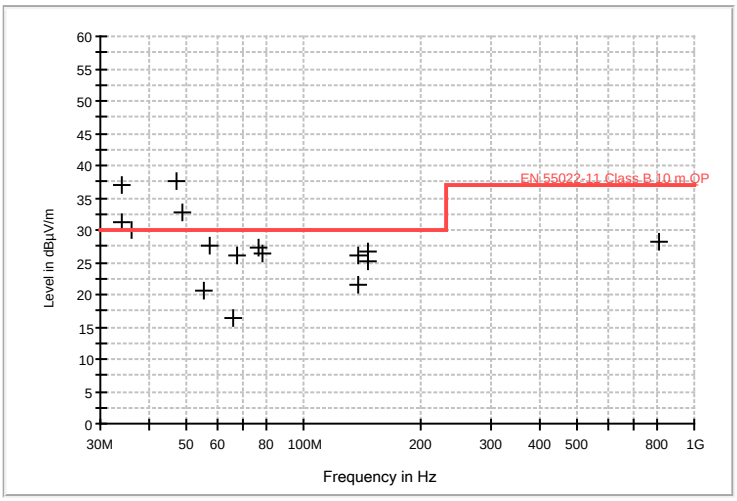
Indicates failure.



Implant Only

Frequency (MHz)	Antenna Polarization	Reading (dBµV)	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
33.990000	V	19.2	17.8	37.0	30.0	7.0
34.000000	H	12.2	18.9	31.1	30.0	1.1
36.030000	V	13.5	16.4	29.9	30.0	-0.1
46.960000	V	27.6	10.0	37.6	30.0	7.6
48.970000	H	23.3	9.3	32.6	30.0	2.6
55.030000	V	11.7	8.8	20.5	30.0	-9.5
56.950000	H	18.7	8.9	27.6	30.0	-2.4
65.450000	H	7.0	9.4	16.4	30.0	-13.6
67.400000	V	17.0	9.0	26.0	30.0	-4.0
76.500000	V	18.2	9.2	27.4	30.0	-2.6
78.510000	H	17.2	9.2	26.4	30.0	-3.6
136.890000	H	6.2	15.2	21.4	30.0	-8.6
137.330000	V	11.0	15.1	26.1	30.0	-3.9
145.300000	V	12.5	14.2	26.7	30.0	-3.3
146.42	H	0.00	14.50	14.5	30.0	-30
808.90	V	0.00	27.60	27.6	37.0	-30

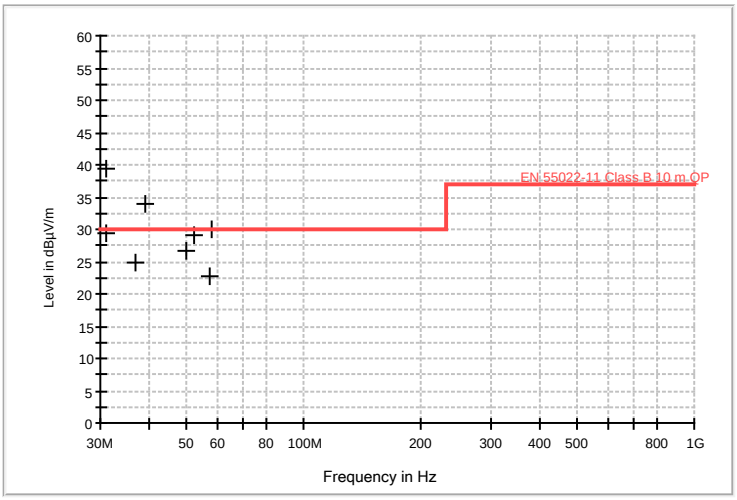
Indicates failure.



No Stem Implant Only

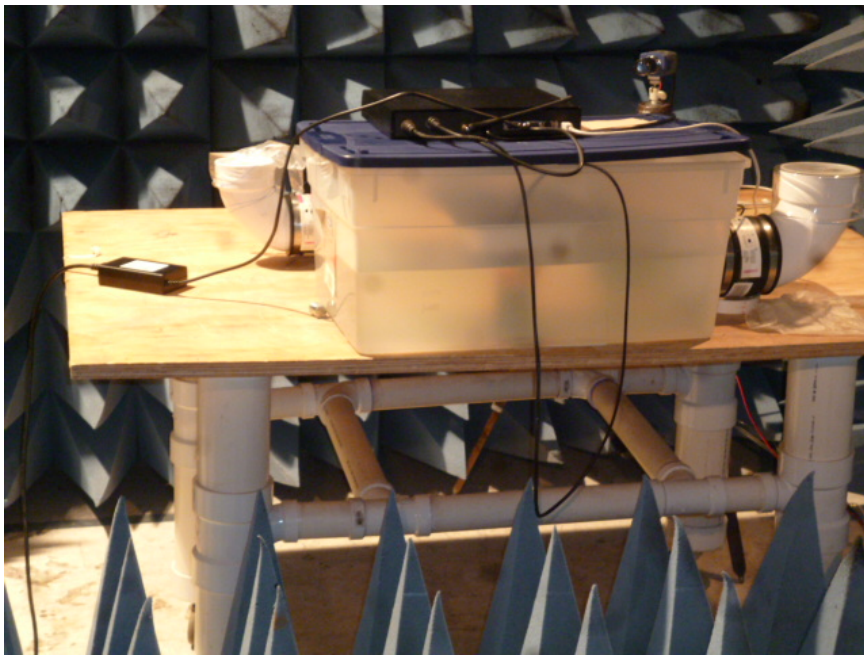
Frequency (MHz)	Antenna Polarization	Reading (dBµV)	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
30.900000	H	8.4	21.1	29.5	30.0	-0.5
30.960000	V	19.0	20.3	39.3	30.0	9.3
36.960000	H	8.1	16.7	24.8	30.0	-5.2
38.960000	V	19.7	14.3	34.0	30.0	4.0
49.940000	V	17.6	9.0	26.6	30.0	-3.4
51.990000	H	20.4	8.8	29.2	30.0	-0.8
56.960000	V	13.6	9.0	22.6	30.0	-7.4
57.910000	H	20.9	9.0	29.9	30.0	-0.1

Indicates failure.



10.3 Photograph(s) of the Radiated Emissions Test Setup

Pre-scan



OATS