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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix I – Battery Testing and Heating Characterization

I. Appendix I – Battery Testing and Heating Characterization

This section contains:

I.1. Overview and Conclusions

A key feature of the NNP System is the presence of an implanted power source capable of providing the power to the entire implanted network. This feature is accomplished with the use of three Quallion LLC Li-ion rechargeable batteries. As described in the Risk Analysis, the presence of the rechargeable battery represents one of the higher levels of risk for the NNP System due to the possibility of heating associated with these cells, particularly in the event of a short circuit. In order to mitigate these concerns, we have carefully chosen cells that include a number of safety features for active implantable medical device use, and we have conducted testing to characterize heating under simulated use conditions.

Three general categories of testing have been performed on the QL0200 cell and associated recharging circuitry: 1) qualification tests performed on these cells at Quallion, LLC, 2) charge/recharge characterization tests performed on these cells at CWRU, and 3) charge heating characterization and testing performed on the power module at CWRU.

From these test results, we conclude:

- The Quallion QL0200 Li-ion rechargeable cell meets all the criteria for an implantable medical grade battery. Multiple levels of risk mitigation, including mechanical, electrical hardware and software are utilized to maintain safe operation of these batteries for the lifetime of the user.
- The Power Module meets the criteria for safe temperature rises for both charging and discharging, exhibiting < 2 deg.C rise without software limits in place (e.g., single-fault condition).
- A maximum external coil temperature of 2.56° C in a 24 hour period, under worst-case, in-air testing. Even when completely uncoupled the external coil does not exceed 4° C.

As noted in *Section 6.4 Anticipated Changes to the IDE*, we anticipate a number of improvements to the power management system of the NNP based on the experience gained in this Early Feasibility IDE. As we learn about real-world patterns of use of the NNP by our study subjects, we can further refine our expectations around run-time, which in turn will drive expectations around recharge frequency and duration. In addition, as we refine our test methods for characterizing heating, we will be able to develop a temperature-based closed-loop recharging feature that minimizes recharge time based on safe heating levels.

I.2. Key Features of Quallion LLC Li-Ion Rechargeable Batteries

Quallion LLC has been developing and manufacturing highly reliable lithium rechargeable cells for medical, aerospace, and specialty applications [Tsukamoto, 2003; Kishiyama et al., 2003; Dodd et al., 2003]. Some key technologies developed at Quallion and incorporated into the design of their lithium rechargeable batteries include:

1) Leakage Reliability,
2) Self-Extinguishing Electrolyte System,
3) Mechanical Impact Resistance,
4) Deep Discharge Storage and
5) High Reliability Manufacturing.

These features are briefly described below and serve to outline the features tested by Quallion on this cell line. Each QL0200 cell comes with a certificate of conformance from

Quallion LLC. The cells are manufactured within a documented system in general accordance with the requirements of ISO-9000.

I.2.1.Leakage Reliability

An area of concern for medical applications is electrolyte leakage, which can jeopardize safety or lead to premature performance degradation. To address this issue, Quallion has focused heavily on the development of a hermetically sealed battery design that provides the required electromechanical stability as well as test methods for process control and quality assurance. One of the key components that differentiate the Quallion design from conventional designs is the ceramic sealed feedthrough. Quallion has chosen to use a feedthrough pin made of platinum-iridium alloy, which has superior electrochemical stability in organic solvent compared to the conventional design which employs a molybdenum pin material [Tsukamoto, 2003]. In addition to the change in material, welding of the feedthrough seam is performed under a controlled process and subjected to an extensive helium leak test using MIL STD 202F. It should be further noted that these sealed batteries are themselves placed in a sealed capsule, the Power Module.

I.2.2.Self-Extinguishing Electrolyte System

The organic electrolyte in Li-ion batteries is a flammable component inside the battery and potentially a source of risk. Quallion has developed a type of liquid-form self-extinguishing (SE) electrolyte that is especially engineered to act as a flame retardant without interfering with the expected function of the electrolyte. One of the components in the system, which is non-miscible with the electrolyte, functions similarly to a 'fire blanket' to contain and quench any abnormal thermal activity. Hence, it allows the cell to perform as designed in different temperature ranges without the same high flammability hazards [Tsukamoto, 2003].

I.2.3.Mechanical Impact Resistance

In general, rough handling, high shock or vibration can result in cell damage, reduced reliability and safety breakdown. To address this, Quallion batteries incorporate a metal mandrel core that serves three important functions: 1) provide a resistant layer against mechanical shock to prevent an internal short-circuit, 2) serve as a heat sink to minimize localized heat buildup, 3) homogenizes the pressure between electrode layers throughout the cell element.

I.2.4.Deep Discharge Storage

For the NNP application, it is important for the battery to have the capability to be kept for prolonged periods of time in a deep discharge state without performance loss or safety risk. This could happen, for example, if a user has a prolonged illness and does not charge the implanted system. The Quallion battery can be held for long periods in a deep discharged state at body temperature without suffering significant loss of capacity, in contrast to conventional Li-ion batteries.

I.2.5.High Reliability Manufacturing

The Quallion manufacturing system is designed to meet the high reliability criteria of medical device and aerospace companies with 100% component and process traceability. Individual cells are uniquely serialized and subjected to an extensive group of in-line and final tests including x-ray inspection, MS/He leak analyses and rigorous electrical assessment. Lot samples are pulled for reliability testing and device history records are carefully maintained and archived for quick retrieval as needed. Each cell is shipped complete with its own certificate of conformance and electrical test data.

I.3. Cell Characterization Testing

The test designs for battery cell testing performed at Quallion are presented in the tables below (Tables I-1 through 3). Tests performed include Mechanical, Electrochemical, Environmental, Safety, and Storage. Battery cell testing at Quallion is conducted according to the following industry standards:

- MIL-STD-202F, Method 103B, Test Condition B;
- prEN 45502-2-1, Section 23.2;
- prEN 45502-2-1, Section 23.7; and
- UL 1642.

In-house protocols (developed at Quallion) are used when required, including the Quallion DC Impedance Test and Quallion Nail Penetration Test.

TEST RESULTS

The results of battery cell testing at Quallion are presented in Tables I-1, I-2 and I-3. The reasonably useable cycle-life of the Quallion cells when used in a typical NNP System is in excess of 3,000 cycles at 100 mA charge, 100mA discharge and 70% depth of discharge.

SUMMARY

The Quallion QL0200 Li-ion rechargeable cell meets all the criteria for an implantable medical grade battery. Each cell is manufactured with high quality and reliability. Multiple levels of risk mitigation, including mechanical, electrical hardware and software are utilized to maintain safe operation of these batteries for the lifetime of the user.

Table I- 1: Quallion AL012001-A Product Testing

Properties	Conditions	Requirement	Outcome
Mechanical			
Dimensions	N/A	Thickness: 5.5 +/- 0.3mm; Width: 17.0 +/-0.2mm; Length: 35.0 +/-0.2mm	Pass
Weight	N/A	Maximum 8.0 g	Pass
Case Material	N/A	Titanium 6Al-4V	Pass
Case Polarity	N/A	Positive	Pass
Feedthru Material	N/A	Molybdenum	Pass
Feedthru Polarity	N/A	Negative	Pass
Cell Marking	N/A	Serial Number; Lot number; Model number	Pass
Hermeticity	Bubble Test per TM 0054	No bubles (BOL and EOL Cells)	Pass
Hermeticity	Bomb Test per TM 0053	Maximum helium leak: 5x10-8 atm-cc/sec (BOL and EOL cells)	Pass
Feedthru Pin Strength	Subject to three cycles of 90° unsupported bends from vertical to horizontal in one direction and a 9 N push force in the axial direction without breakage	Meet hermeticity requirement: maximum helium leak of 5 x 10-8 atm-cc/sec	Pass
Safety			
UL 1642	UL 1642	The cell shall pass all tests listed in UL 1642 that apply to technician-replaceable secondary lithium cells with no mechanical detachment	Pass
Nail Penetration	TM 0041	The cell shall pass the Quallion nail penetration test per test procedure TM 0041 with no mechanical detachment	Pass
Storage			
Storage	Storage at 25°C for 6 months	Minimum discharge capacity using standard cycle at 37°C for capacity check = 170 mAh	Pass

* All tests and measurements are taken at 30%-50% relative humidity and 25 +/-5degC unless otherwise noted
* BOL Cells = Cells stored at shipment charge at room temperature for less than 3 months from the manufacturing date.
* EOL Cells = Cells at shipping charge after 500 standard cycles.

Table I- 2: Quallion AL02001-A Product Testing - Environmental

Properties	Conditions	Requirement	Outcome
Environment			
Humidity	Test exposure of 96 hours at 95% humidity, non-condensing, at 40+/-2°C per MIL-STD-202F, Method 103B, Test Condition B	Cells shall have a minimum discharge capacity of 162mAh measured using a Standard Cycle at 37°C. In addition, they shall meet all requirements specified in section 5.1 (mechanical)	Pass
Vibration	Random vibration of 5-500Hz, ASD spectrum level 0.7 m2/s4 for duration of 30 minutes each in the three mutually perpendicular directions per prEN 45502-2-1, Section 23.2	Cells shall have a minimum discharge capacity of 162mAh measured using a Standard Cycle at 37°C. In addition, they shall meet all requirements specified in section 5.1 (mechanical)	Pass
Mechanical Shock	Six half-sine shock impulses per axis (1 per axis direction) of 500G magnitude, 1ms duration per prEN 45502-2-1, Section 23.7	Cells shall have a minimum discharge capacity of 162mAh measured using a Standard Cycle at 37°C. In addition, they shall meet all requirements specified in section 5.1 (mechanical)	Pass
Drop Test	A drop once from a height of 3 fee onto linoleum covered concrete floor on any major axis (The feedthru pins shall be protected from direct impact during the drop test)	Cells shall have a minimum discharge capacity of 162mAh measured using a Standard Cycle at 37°C. In addition, they shall meet all requirements specified in section 5.1 (mechanical)	Pass

* All tests and measurements are taken at 30%-50% relative humidity and 25 +/-5degC unless otherwise noted

* BOL Cells = Cells stored at shipment charge at room temperature for less than 3 months from the manufacturing date.

* EOL Cells = Cells at shipping charge after 500 standard cycles.

Table I- 3: Quallion AL02001-A Product Testing - Electrochemical

Properties	Conditions	Requirement	Outcome
Electrochemical			
Capacity	At 37°C; Standard Charge; 5 minutes rest; Standard Discharge	Nominal discharge capacity: 200mAh; Minimum discharge capacity: 180mAh	Pass
Voltage	N/A	Nominal 3.6 V	Pass
Normal Operating Voltage Range	N/A	2.5 V -> 4.1 +/-0.01V	Pass
Operating Temperature	N/A	32°C - 42°C	Pass
Limited Operating Temperature	Charge/Discharge of more than 10 cycles may impact cycle life	10°C - 32°C	Pass
Preferred Storage Temperature	N/A	10°C - Room Temperature	Pass
Charge Current	N/A	Maximum 100mA (BOL and EOL)	Pass
Discharge Current	N/A	Maximum 200mA (BOL and EOL)	Pass
AC Impedance	Measured at 1KHz after Standard Discharge	Maximum 1 Ω; Maximum 0.5 Ω at BOL	Pass
DC Impedance	DC Impedance Test**	Maximum 2 Ω	Pass
Cycle Life	500 Standard Cycles at 37°C; 1 Standard Cycle at 37°C to check capacity	Minimum discharge capacity measured using the Standard Discharge after the storage: 126mAh	Pass
Self-Discharge	Standard Charge at 37°C; 90 days storage at 37°C; Standard Discharge at 37°C	Minimum discharge capacity measured using the Standard Discharge after the storage: 144mAh	Pass
Calendar Life	Standard Charge at 37°C; Store at 37°C for 1 month; Check capacity at 37°C after each month of storage by the following: standard discharge, 5 minutes rest, standard cycle; Standard Discharge at 37°C and repeat storage at 37°C	Minimum discharge capacity measured using the Standard Cycle after 3 months storage: 153mAh	Pass
Zero Volt Discharge	Standard Charge at 37°C; At 37°C, discharge cell with external resistance (30-100 Ohm) for 30 days; At 37°C, 10mA trickle charge until cell voltage reaches 2.5V; Standard Cycle at 37°C	Minimum discharge capacity measured using the Standard Cycle: 162mAh	Pass

* All tests and measurements are taken at 30%-50% relative humidity and 25 +/-5degC unless otherwise noted

I.4. Battery Charge-Discharge Testing

Charge-Discharge testing was performed at CWRU. Implantable grade lithium ion cells from Quallion were tested under multiple charge/recharge cycling conditions using an Arbin BT2000 test station at 37° C [Purushothaman, 2006]. The conditions for maximizing cycle life were determined. In general, to maximize the cycle-life of the cells, one should use the lowest charge and discharge current rates, and the lowest depth of discharge.

Table I- 4: Battery Charge-Discharge Testing (CWRU)

Test Name	Conditions	Results
Discharge Capacity as a Function of Cycles	C/5 Charge Rate; 4.1 V charge; C Discharge Rate; 2.75 V disharge voltage cutoff 2.75 V; At 37°C; 100% Depth of Discharge	EODV = 0.2 - $1.5x10^{-3}(cycle)^{0.5}$
Loss in capacity after deep discharge cycling	C/5 Charge Rate; 4.1 V charge; C Discharge Rate; 2.75 V disharge voltage cutoff 2.75 V; At 37°C; 100% Depth of Discharge	220 cycles @ 10% Capacity Loss; 820 cycles @ 20% Capacity Loss; 1710 cycles @ 30% Capacity Loss
Cycle Life at shallow DOD (60%)	C Charge Rate; 4.1 V charge; C Discharge Rate; 2.75 V disharge voltage cutoff 2.75 V; At 37°C; **60% Depth of Discharge**	EODV = 3.75 - $1.6x10^{-4}N$; 6000 cycles to EODV (2.8 V)
Cycle Life at low charge/discharge	C/4 Charge Rate; 4.1 V charge; C/4 Discharge Rate; 2.75 V disharge voltage cutoff 2.75 V; At 37°C; 80% Depth of Discharge	EODV = 3.39 - $9.0x10^{-5}N$

Test results of the cycle life testing are shown in the Figure that follows, below. Example charge-discharge cycles at 10, 1000, 2000 and 4000 cycles are shown.

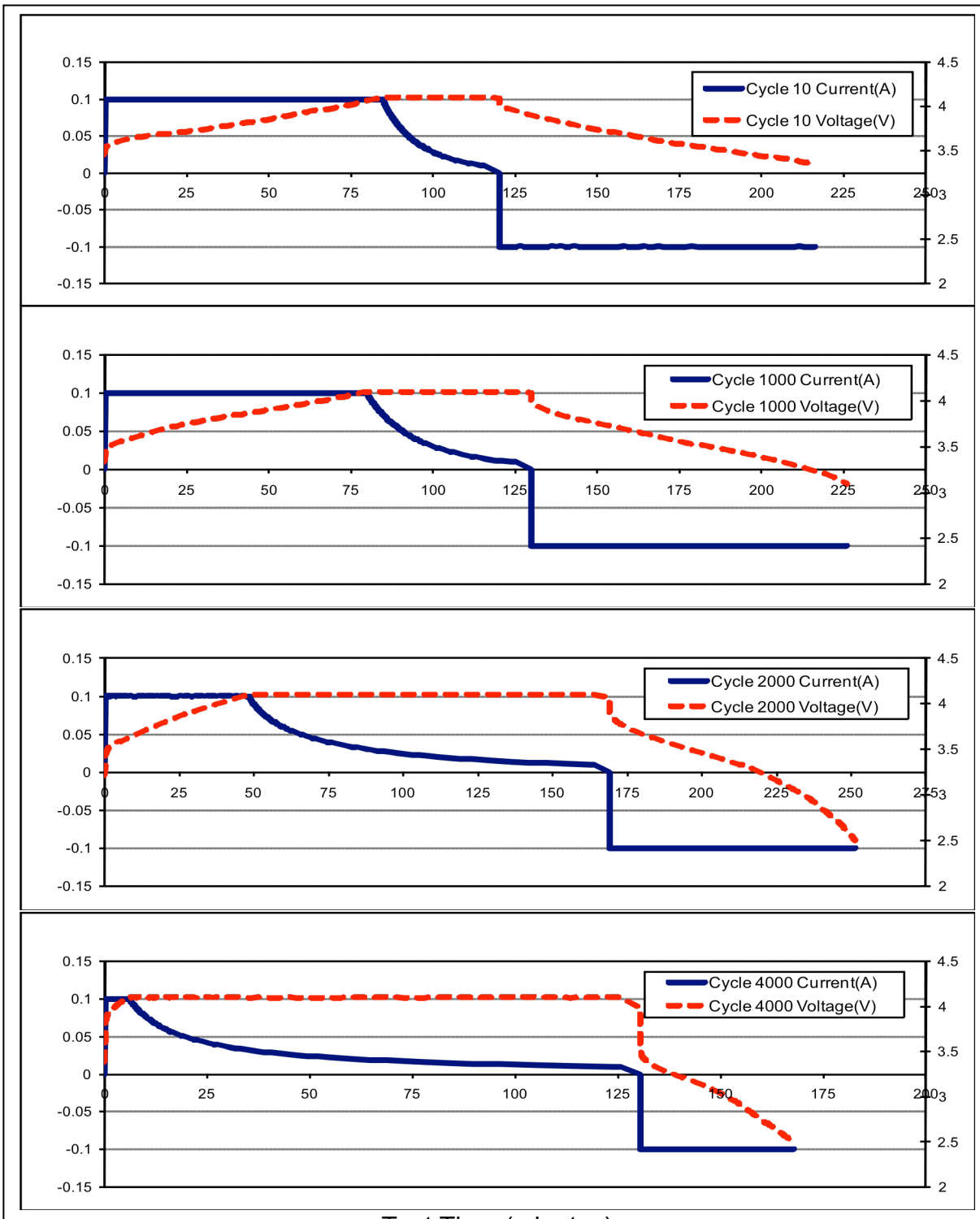


Figure I-1. Q200 Li-ion charge-discharge cycles. Conditions were 80% depth of discharge, 100mA charge and 100mA discharge. The left axis (blue solid line) shows current and the right (red dashed line) shows voltage. Successive graphs from top to bottom show cycle #10, #1000, #2000, and #4000. These tests were conducted over a 2.5-year period.

I.5. Recharge Heating Characterization

As noted in our Risk Analysis, inductive recharging carries a risk of overheating the Power Module case, the external coil, or both. Heating of the external coil is considered the higher risk (RPN in the Intolerable Region, > 10); it will be discernable during our in-clinic supervised recharging sessions and adjustments to the external coil (placement, spacer materials) can be made if necessary.

Heating of the Power Module has several potential causes:

- Eddy currents when the external coil is on and near the Power Module or other active component;
- Current regulators in the charging circuitry;
- Implant circuitry (e.g., microcontroller, radio) when the Power Module is active; and
- Network drive when the remote modules are active.

If the magnetic field is larger than it needs to be, the eddy-current heating will predominate, and the temperature rise will increase even as the batteries enter constant voltage charging and the device utilizes less of the magnetic field. To minimize temperature rise, the magnetic field sensed by the Power Module coil should be the minimum necessary to support the desired charging current. This is achieved by increasing the space between the charge coil and the implant, or by reducing the drive voltage of the charge coil.

In characterizing recharge heating, we have conducted two sets of tests. The first tests were conducted in air – considered to be a worst-case condition – and were previously provided in our pre-IDE (I111144). (These are also provided in Section I.5.2, below, for completeness.) The second set of tests was performed in a more realistic simulated condition, a saline phantom that features both a "torso" and an "arm." These more realistic tests are being used to inform design refinements for the external coil and power management features of the NNP.

I.5.1. Recharge Heating Characterization in Saline Phantom

PURPOSE

The purpose of this test is to demonstrate that the temperature rise of the implant, as experienced by the subject, during charging and discharging is safe, even without the application of software limits (e.g., single-fault condition).

METHODS

The Power Module was placed in the saline phantom with it's top face ~11mm below the surface of the water. The Charging Coil was placed ~16mm above the surface of the water with an air gap between the coil and the Power Module to minimize heat transfer to the phantom and implant that would contaminate the heat resulting from the implant alone. The Charging Coil was driven at 6V. The magnetic field was sufficient to support charging currents of 45-50mA per cell (target <4hour charge).

The Power Module contains a thermistor placed in direct contact with the titanium case closest to the surrounding tissue, which will serve as the primary control signal for a (future) temperature-based closed-loop control algorithm to allow maximal recharge at safe tissue heating levels. This thermistor effectively measures the inner capsule temperature,

which is a combination of the ambient electronics temperature and the inner surface of the titanium capsule. During the test, however, heating limits were characterized through the use of multiple thermocouples:

- Thermocouple 1 was placed on the outside of the capsule roughly above where the thermistor is welded. Thermocouple 1 was placed such that the exposed metal made as much contact with the capsule surface as possible and was covered in polyamide tape to keep it in place. **Thermocouple 1 is considered the closest measure of implant surface temperature as specified in ISO14708-1**.
- Thermocouple 2 was placed near (~1cm) the Power Module capsule, roughly at the same depth as the PM (e.g. not above or below).
- Thermocouple 3 was placed far from the Power Module capsule but not along a wall of the phantom, so as to provide a stable reference in saline
- Thermocouple 4 was placed in air near the phantom to record room temperature fluctuations

Thermocouple 3 was used as a reference. The temperature delta was measured as the difference between temperature from Thermocouple 1 or 2 or Thermistor and temperature from Thermocouple 3 (the Thermistor data was resampled to match the thermocouple data rate). Fixed offsets for all thermocouples were measured relative to the average for all thermocouples when placed very close in the same liquid (negligible true temperature difference between sensors). A fixed offset between Thermocouple 1 and the Power Module Thermistor was obtained while the Power Module was in air and in a steady state (not charging or driving network). The saline phantom temperature was not controlled other than by the room HVAC system, which maintains the room temperature to within ~1degC. Due the large thermal time constant of the saline phantom, the variability in the saline temperature is much lower.

CRITERIA

ISO14708-1 (2000) specifies that no outer surface of an implantable part of an active implantable medical device shall be greater than 2 deg. C above the normal surrounding body temperature of 37 deg.C when implanted, and when the active implantable medical device is in normal operation or in any single-fault condition. In comparison, for skin-contacting devices, IEC 60601-1 calls out a 41 deg.C limit, but further acknowledges that safe temperature exposure is a function of both time and temperature. In choosing to maintain a < 2 deg.C limit on temperature rises to the outer surface of the implant, we are using the more conservative criterion for safe heating.

RESULTS

As shown in Figures I-2 and I-3, below, aggressive charging resulted in a 1.2 deg.C rise on the outer surface of the capsule during charging and 1.1 deg.C rise during discharging. The internal thermistor reading of 2.2 deg.C during charging, and 2.1 deg.C during discharging, provides an ample safety margin as a potential control signal for a future closed-loop feature.

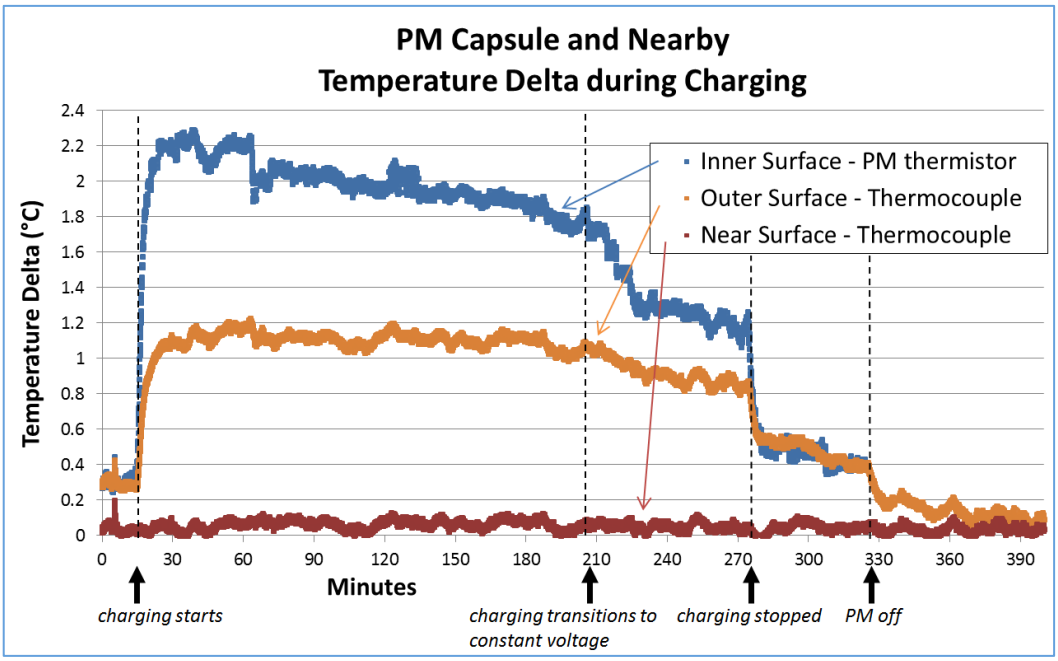


Figure I- 2. Power module temperature rise during charging.

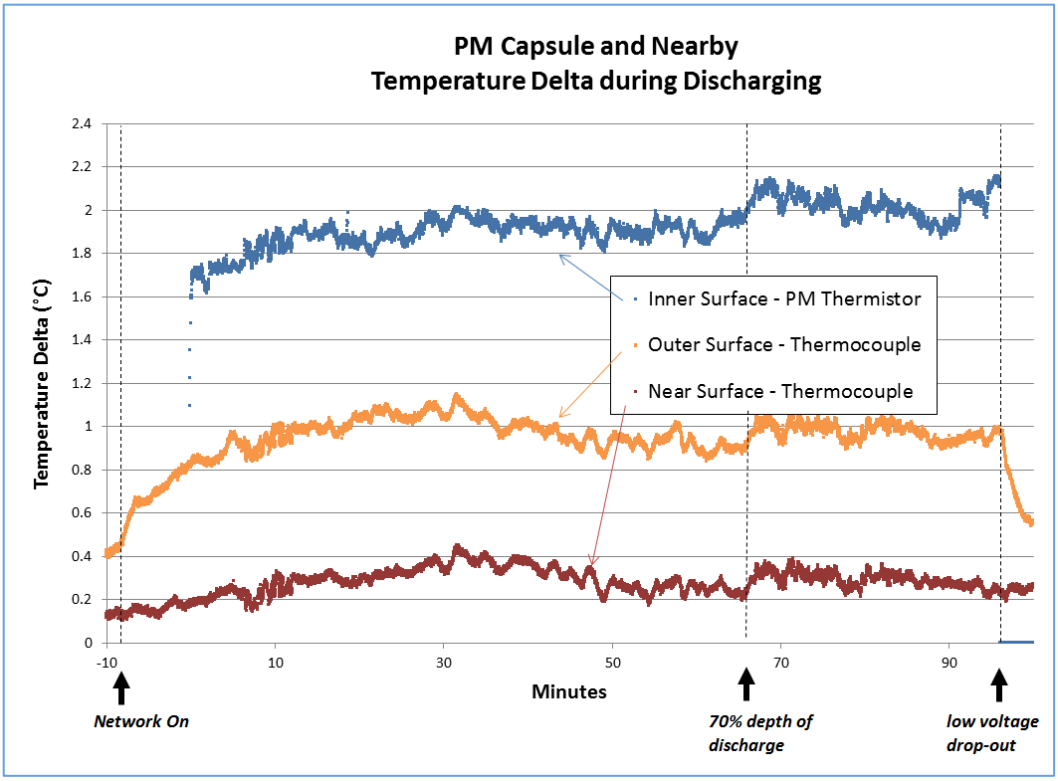


Figure I- 3. Power module temperature rise during discharging.

CONCLUSIONS
The Power Module meets the criteria for safe temperature rises for both charging and discharging, exhibiting < 2 deg.C rise without software limits in place (e.g., single-fault condition).

I.5.2.Recharge Heating Characterization in Air

[This test represents the original heating characterization testing provided in our pre-IDE submission, I111144, and is provided for completeness.]

PURPOSE
A key feature of the NNP System is the use of implanted battery power supplied by three Li-ion rechargeable cells housed in the power module. Recharging of the cells is accomplished via an inductive coil placed on the skin over the Power Module. Inductive recharging carries a risk of overheating the Power Module case or the external coil, or both. In order to mitigate this risk, we performed a series of recharge tests to set a maximum limit for charging output that maintained the components below the established standards for safe tissue heating. The charging limit is implemented in the electronic hardware of the Control Tower charging circuit. As a result, safe recharge is ensured through hardware design.

TEST DESCRIPTION
The recharge heating test was performed using an experimental set up that included the Power Module enclosure and receive coil, the external charging coil, drive circuitry and thermocouples. The Power Module enclosure was placed flat on a non-conductive surface with a thermocouple attached to the top surface to record case surface temperature. The internal coil of the Power Module was monitored via leads exiting the case. This provided a direct measure of the received power and current developed in the internal coil, enabling direct calculation of the expected rate of recharge for each test condition. The inductive recharge coil was placed 3cm above the top surface of the Power Module case and was suspended in place with air between the bottom surface of the coil and top surface of the Power Module enclosure. The test was performed at room temperature with no active air circulation around the components. This configuration represents a worst case in regard to heating of the case. The perfusion of living tissue provides considerable heat transfer in contrast to non-circulating air [Okazaki et al., 1997; Seese et al., 1998].

Heating of all components was recorded with thermocouples attached to the Power Module, coil and suspended in the room (ambient). Thermocouples were attached to the Power Module (top surface, long side, short side) and to the transmit coil (bottom center, bottom edge, side), as shown in Figure I-4. One thermocouple was suspended in the air gap between the coils and one thermocouple was suspended in free air at a distance of approximately 20 cm from the center of the two coils.

The inductive drive and power recording setup is illustrated in Figure I-5. The power transfer across the inductive link formed by the transmit coil and Power Module, which contains the receive coil, was determined. The inductive link operates as a series tuned primary and a series tuned secondary. The resonant frequency of the link was 3.48 KHz. The transmit coil/capacitor was driven by the coil drive amplifier (square wave) at the resonant frequency. The coil drive amplifier DC voltage and current were recorded during the experiments. The AC current in the transmit coil was measured with a current probe

(Tektronix AM503B) and also recorded. Coil current was set by the coil drive amplifier DC voltage. The output of the receive coil was rectified and filtered. This DC output was connected to a variable resistive load and measured on an oscilloscope.

The coil drive voltage was set to develop a range of received power levels, from 200 mW to 2000 mW. Starting at the highest charge rate, the power to the inductive coil was delivered continuously while temperature was monitored and recorded. When the temperature of the Power Module case increased by 4°C over ambient the test was stopped and the results recorded. The components were allowed to cool to room temperature and the test was repeated with a lower recharge current. In a subsequent test, delivery of the lowest received power level (200 mW) was maintained at a constant level for a period of 24 hours in order to verify that the patient could leave the coil in place long term without any detrimental heating effects.

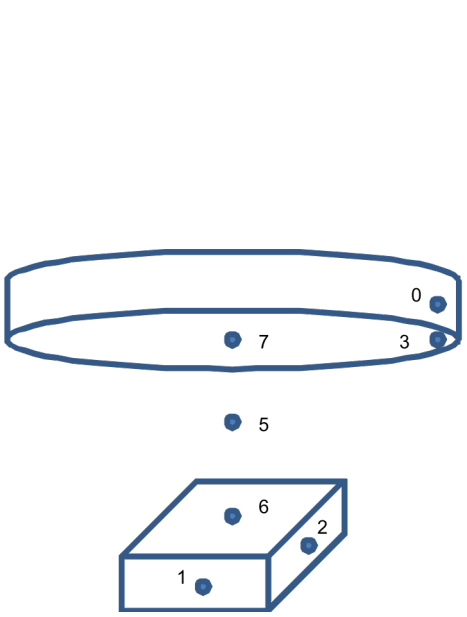


Figure I-4. Location of thermocouples for the experimental setup for recharge heating test. The rectangular box represents the Power Module and the cylinder represents the external charging coil.

TEST RESULTS

The results of the recharge heating test are shown in Figure I-6. It was determined that a received power level of 200 mW enabled the coil to continuously recharge without excessive heating of the Power Module case or the external coil. At a received power of 200 mW, the Power Module case temperature increased 1.2°C over ambient temperature in the first 30 minutes of recharging and then plateaued. At 300 mW received power, the Power Module case exceeded the 2°C increase after approximately one hour of recharging.

The results of the 24-hour testing of the inductive link at a received power level of 200 mW are shown in Figure I-7. This data indicates that the Power Module never exceeded an increase of 1.74°C over ambient and the external coil never exceeded 2.56°C over ambient during the entire test period. These values are below the heating thresholds established by

standard BS EN 45502-2-2:2008. These standards recommend that the outer surface of an implant should not be >2°C over normal surrounding temperature. The external components should not be >4°C over normal surrounding temperature.

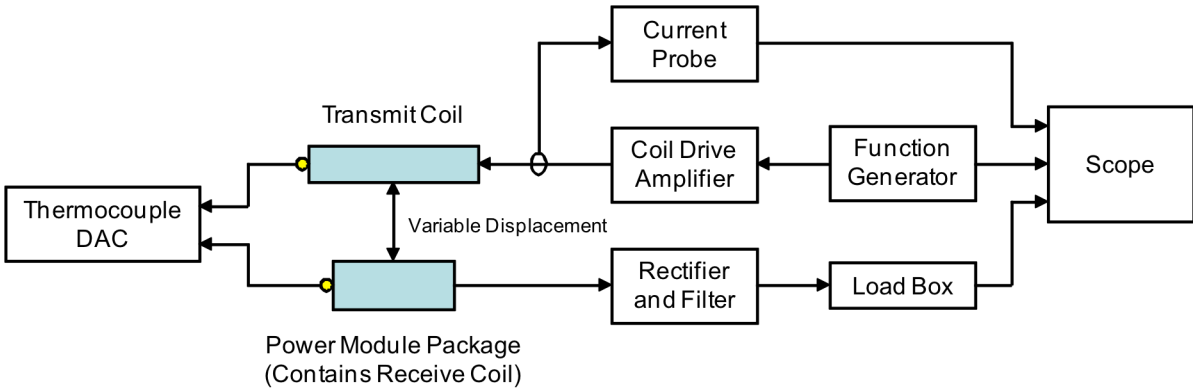


Figure I-5. Experimental setup for driving the inductive link and measuring received power.

Based on these results, the Control Tower was designed to supply a maximum received power of 200 mW at the Power Module. This is accomplished by setting the maximum coil drive amplifier output to 4.7 VDC and requiring the separation between the external coil and Power Module to be 3cm or more. This minimum distance is established by adding padded spacers to the external coil to maintain the appropriate minimum distance. Assuming a 70% depth of discharge, a full recharge could be realized in approximately 14 hours.

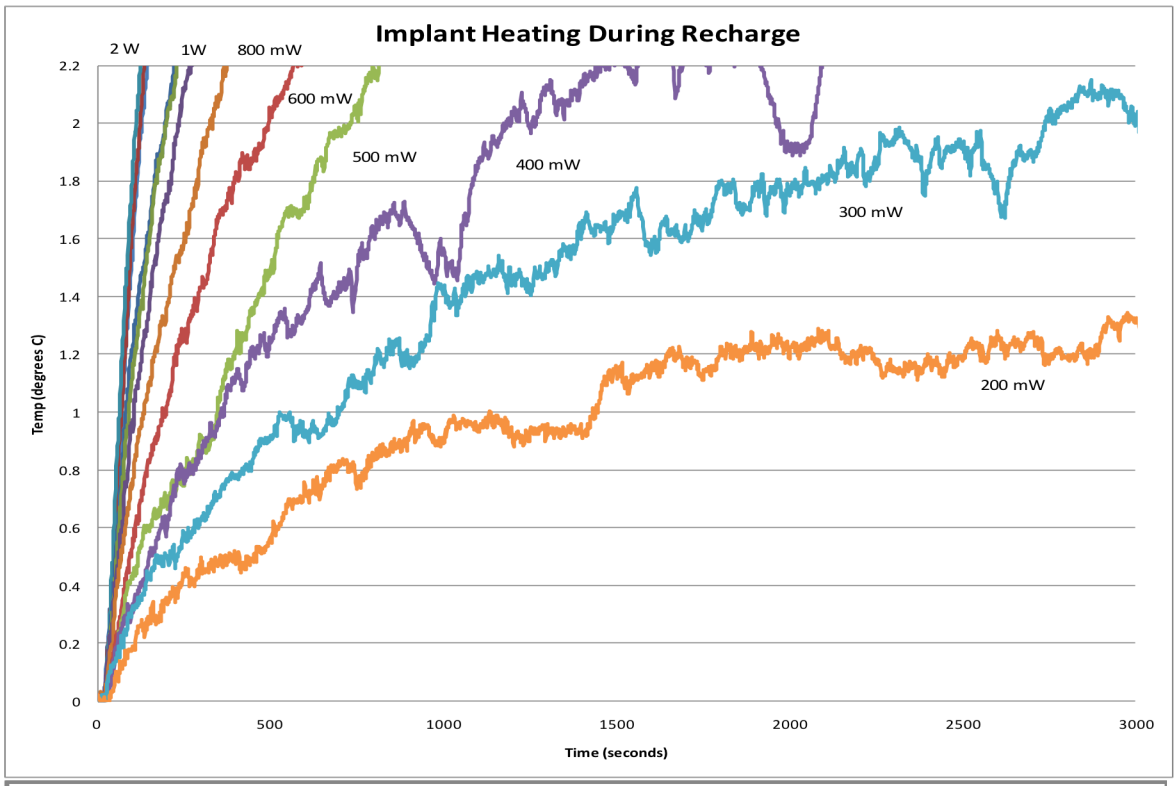
It should be noted that the received power of 200 mW represents a very conservative requirement. First, as mentioned, the perfusion in the body provides a significant buffer for temperature rise within the body. Second, there is considerable evidence in the medical literature that the body can tolerate temperatures as high as 45°C (8°C over normal surrounding temperature) for at least 30 minutes [Martinez et al., 1983; Davies et al., 1994; Seese et al., 1998]. We anticipate pursuing methods of reducing the total recharge time utilizing direct recordings from the power module in-vivo. Thus, in a future Supplement, we may present results describing methods for reducing the total charge time.

CONCLUSIONS

In summary, at a fixed displacement of 3 cm, a 200 mW received power transfer (set by a 4.7 VDC coil drive) yields:

- A maximum Power Module case temperature rise of 1.74° C in a 24 hour period,
- A maximum external coil temperature of 2.56° C in a 24 hour period,
- A 14-hour system recharge time for a fully discharged system.

Displacements greater than 3 cm will yield lower Power Module case temperatures and higher external coil temperatures. However, even when completely uncoupled the external coil does not exceed 4° C. Therefore, the output of the charging circuitry is hardware-limited to 4.7 VDC maximum, providing a direct hardware limit to mitigate any risk of component overheating.



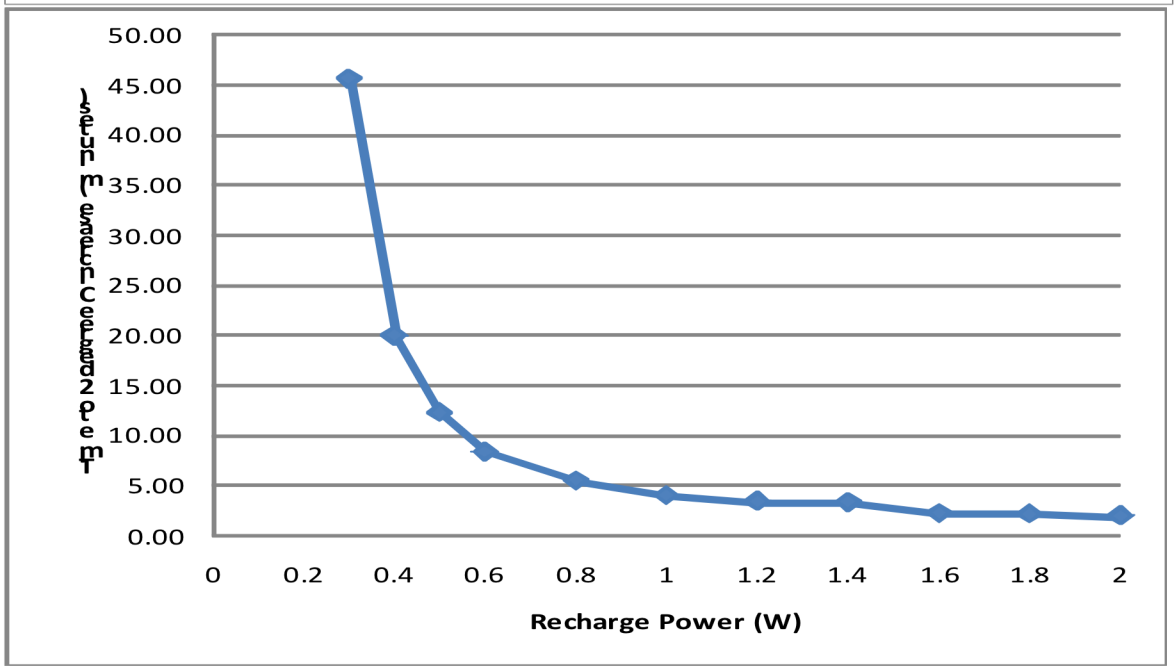


Figure I-6. Power Module case heating as a function of the received power level for charging, **in air**. The top graph shows the case heating as a function of time for different levels of received power, from 200mW (lowest line) up to 2 W (left-most line). The bottom graph shows the time taken to reach the physiological heating threshold of a 2° C increase over ambient. At 200mW, the threshold is never reached.

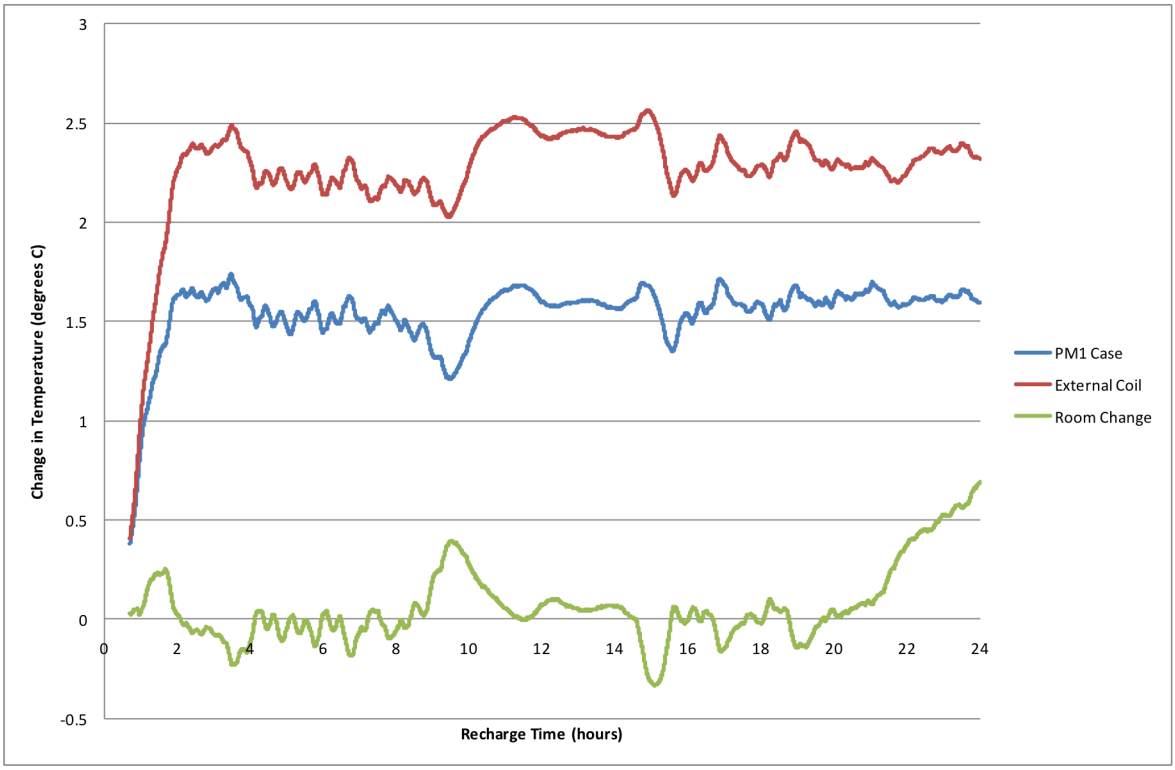


Figure I-7. Power Module Case heating and external coil heating at a received power level of 200 mW over a 24 hour period, **in air**. The top line is the external coil temperature, which never exceeds 2.56° C. The middle line is the Power Module case, which never exceeds 1.74° C over the entire period. The lower line shows the ambient temperature over the 24 hour period.

I.1. Power Module Single-Fault Heating Characterization

PURPOSE
To address FDA concerns about near runaway heating conditions (see Questions 10 and 12, pre-IDE I111144), two tests were performed to characterize the heating and subsequent temperature rise of the Power Module under a single fault condition where excessive current draw occurs from one or more of the cells.

METHODS
In both tests, a complete Power Module assembly was immersed in the saline-phantom test apparatus. Thermocouples were placed at several positions, both internal to and external to the Power Module capsule and then the appropriate fault condition was induced and temperature rises were recorded.

Test 1
The test is designed to assess the temperature rise at the external surfaces of the Power Module when all three cells are sourcing current at a level just below the circuit protection threshold. The maximum current draw from each cell is limited by the action of the series connected resettable polymeric PTC fuses, Littelfuse 1206L050.

At nominal room temperature, these fuses are designed to open-circuit at 500 mA. However, at 37 °C, and after re-rating for elevated temperature usage, the fuses limit current sourced from each cell to approximately 400 mA. This gives a continuous, aggregate current draw of 1,200 mA for the three-cell battery for a single-fault condition on the Power Module PCB.

A complete Power Module with three fully-charged cells was modified to have individual resistive loads applied to each cell to approximate the maximum current draw to that of the re-rated fuse, 400mA each. The resistive loads were sized such that the average current draw approximated a continuous current draw of 400 mA from each cell for the duration of the experiment. The power dissipated by the resistive loads was contained within the Power Module capsule and causes the Power Module to heat.

Thermocouples were placed on the top and bottom external surfaces of the of the Power Module capsule. In addition, the Power Module's own internal thermistor was also monitored during the experiment. The aggregate current draw from the cells was also monitored.

Test 2
To assess the temperature rise experienced in the event of a direct electrical short of a single cell, a complete Power Module was modified to allow a complete, zero-ohm electrical short across the terminals of the center cell. The resultant power dissipated by the shorted cell was contained within the Power Module capsule and caused the Power Module and adjacent cells to heat. The resultant temperature rise of the three cells and the Power Module housing was measured and the mechanical response monitored.

Thermocouples were placed internally on each cell, and thermocouples were placed on the external surfaces of the top and bottom of the Power Module capsule. In addition, the Power Module's own internal thermistor was also monitored during the experiment. The current draw from the shorted cell was also monitored.

The experiment was conducted within the saline-phantom at room temperature. A thermocouple was used to monitor the ambient saline-phantom temperature and the experimental results are presented as referenced to body temperature; ie temperatures plotted are elevated by the difference between the saline-phantom ambient temperature and 37°C.

RESULTS

Test 1 Results

The following graph illustrates the temperatures measured as the three cell battery was discharged from fully-charged to, essentially, fully-discharged with an average 400 mA current draw from each cell.

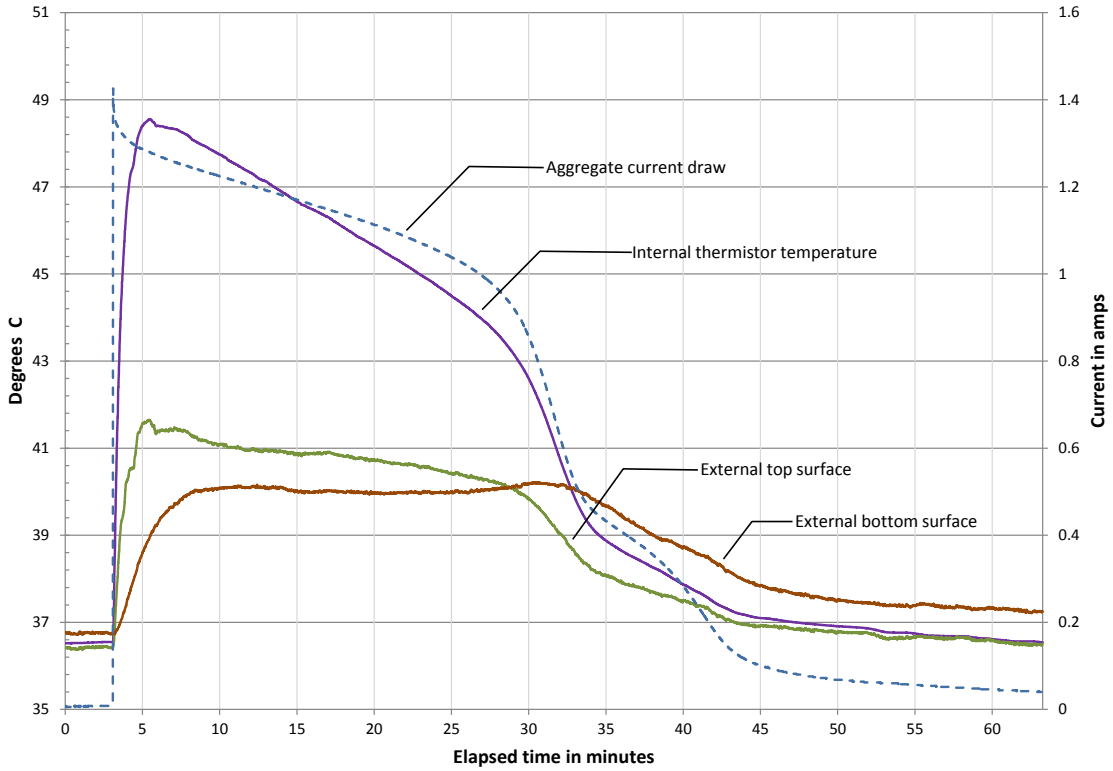


FIGURE I- 8: MEASURE TEMPERATURE DURING NEAR CIRCUIT-PROTECTION THRESHOLD LIMIT

The maximum temperatures measured (referenced to body temperature) on the external surfaces of the Power Module capsule were 41.7 °C on the top surface, and 40.2 °C on the bottom surface. Post experimental evaluation of the three cells showed no discernable physical or mechanical changes resulting from the high-current discharge.

Test 2 Results

The following graph illustrates the temperatures measured as the central cell was rapidly discharged from fully-charged to fully-discharged.

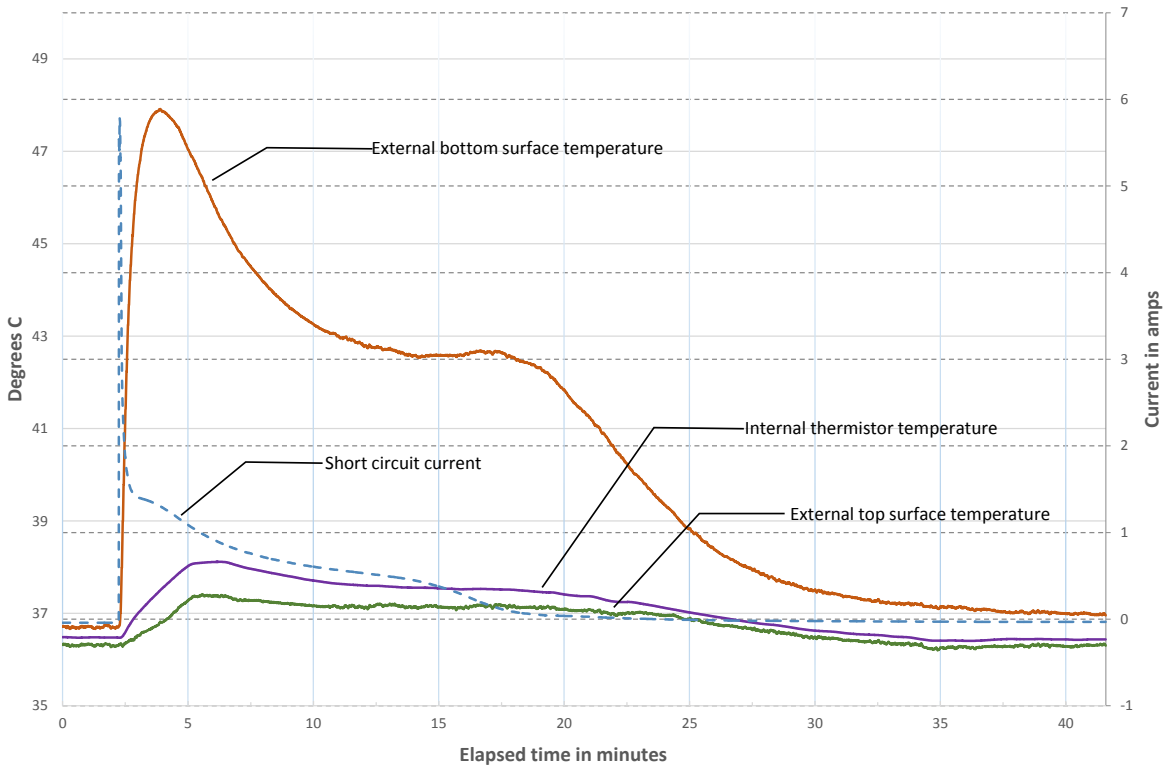


FIGURE I- 9. MEASURED TEMPERATURE DURING DIRECT ELECTRICAL SHORT CONDITIONS

The maximum temperatures measured (referenced to body temperature) on the external surfaces of the Power Module capsule were 37.4 °C on the top surface, and 47.9 °C on the bottom surface. The position of the cells within the Power Module is such that they are significantly closer to the bottom surface of the Power Module; hence, the significant difference of temperature between the two surfaces. Post experimental evaluation of all three cells – including the shorted cell – showed no measureable dimensional changes or discernable physical changes resulting from the high-current discharge.

CONCLUSIONS

Under simulated single-fault conditions of the internal cells, the Power Module experiences temperature rises of its outer surface that exceed the 2 deg.C limit for implants. Referring to Clause 11.1 and Table 24 of IEC 60601-1 (3rd Edition), temperature rises greater than 41 deg.C can be permitted based on shorter duration exposure levels. While that standard refers to skin-contact only, it does suggest that limiting the time exposure to excessive temperatures is a valid strategy. Our testing demonstrates a >2-deg.C rise lasting approximately 35 minutes for Test 1, and approximately 23 minutes for Test 2.

I.2. Prototype External Recharge Coil Heating Test

BACKGROUND
The final design of the External Charging Coil has not been established. As noted in *Section 6.4 Anticipated Changes to the IDE*, we anticipate a number of improvements to the power management system of the NNP based on the experience gained in this Early Feasibility IDE, including possible changes to the configuration of the External Recharge Coil. As we learn about real-world patterns of use of the NNP by our study subjects, we can further refine our expectations around run-time, which in turn will drive expectations around recharge frequency and duration. In addition, as we refine our test methods for characterizing heating, we will be able to develop a temperature-based closed-loop recharging feature that minimizes recharge time based on safe heating levels.

In the test that follows, a prototype design for the External Recharge Coil is tested for temperature rises during a worst-case charging scenario.

PURPOSE
To characterize heating of a prototype External Recharge Coil design under worst-case conditions.

METHODS
The temperature of a first prototype of the External Coil was evaluated during simulated worst-case conditions in which the coil is placed in a location that does not permit power transfer to the implant. This scenario might occur if a caregiver mistakenly holds the coil during charging, or if it is mistakenly placed on the subject's lap during charging. Power in the coil is at its maximum when there is no implant. Because the charge control algorithm does not allow the coil to run for more than 35 seconds if the Power Module does not receive adequate voltage across the link, this test was accomplished by overriding this safeguard, and therefore represents an unlikely worst-case scenario.

RESULTS
The figures below show temperature measurements obtained from a thermistor placed on the outer surface (applied side) of the External Recharge Coil, separated from the coil by about 1/8" of Styrofoam insulation.

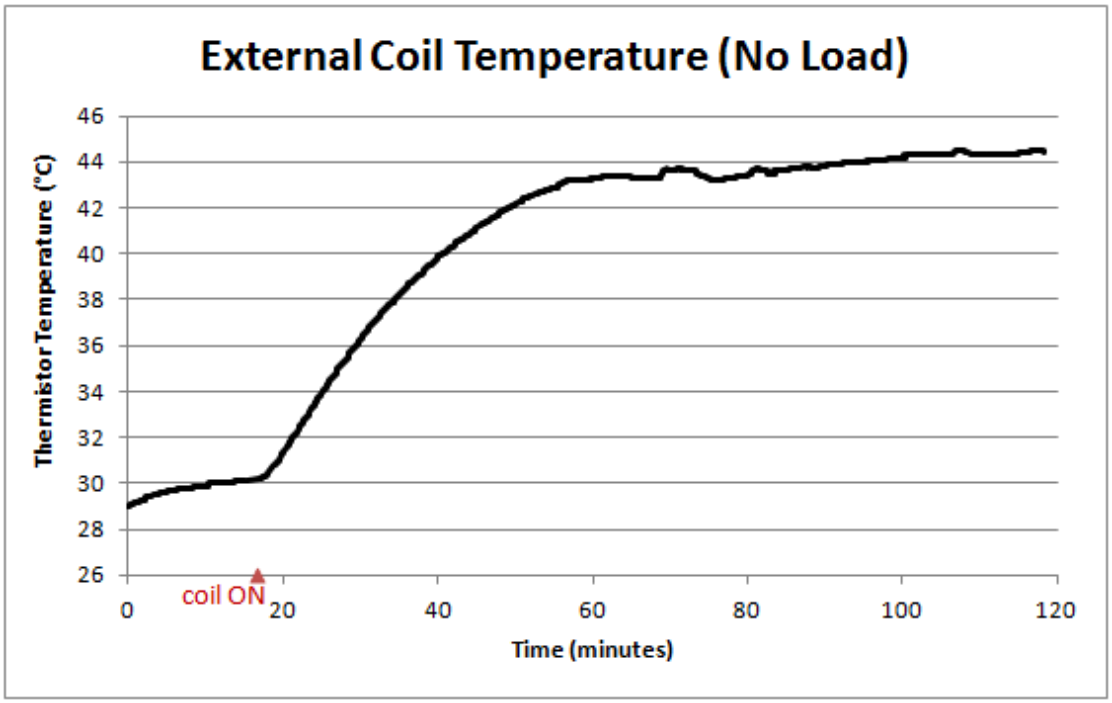


FIGURE I- 10: EXTERNAL COIL TEMPERATURE DURING NO-LOAD CONDITIONS

CONCLUSIONS

External temperature levels greater than 41 deg.C were measured during this test. Referring to Clause 11.1 and Table 24 of IEC 60601-1 (3rd Edition), skin-contacting temperature rises greater than 41 deg.C can be permitted based on shorter duration exposure levels, including permitting temperatures as high as 43 deg.C for durations longer than 10 minutes. In this test, the External Charging Coil just exceeds the 43 deg.C limit, suggesting the need for only minor modifications to the design, which will be the focus of this Early Feasibility IDE study.