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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix J – Mechanical Testing

J. Appendix J – Mechanical Testing

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J.1. Overview and Conclusions

Based on our Risk Analysis and Device Evaluation Strategy, several mechanical tests have been conducted to fully characterize aspects of the NNP System that have not previously been evaluated. These include:

- Tests that establish the mechanical integrity of the headers and feedthroughs of the Power Module, Pulse Generator Module, and Biopotential Module; and
- Tests that establish the mechanical durability and electrical performance of NNP leads and cables.

Please note that we perform hermeticity testing on *all* modules as part of unit qualification. Units that do not pass the acceptance criteria at the time of manufacture are not used.

We have not repeated tests of mechanical durability of previously-IDE-approved electrodes, due to their long history of use and identical manufacturing methods as previous IDE's and PMA's. Please see *Section 4.0 Prior Clinical Studies* and *Section 5.0 Prior In Vivo Studies* for evidence that supports this approach.

In addition, due to cost considerations, we have not conducted destructive testing of our external components, such as performing drop-tests of the Control Tower or Host Computer Network.

J.2. Power Module and Remote Module Feedthrough Testing

GENERAL DESCRIPTION AND PURPOSE

Lidthrough assemblies are utilized in the Power Module, Pulse Generator Module and Biopotential Module. This document describes the testing of the lidthrough assembly for durability.

TEST CRITERIA

Leak testing is performed according to MIL-STD-883. Standard leak rate is to be 2.7×10^{-9} atm-cc/sec helium.

TEST DESIGN

A functional verification was performed to ensure that it was possible to identify leak defect-free and leak defective Power Module lidthroughs. A total of two Power Module lidthroughs were provided for performing fine leak testing as part of the functional verification. Each lidthrough was tested three times and the results were recorded and attached to the tool verification form. Both LTs provided were not leakers. As part of the functional tool verification it was necessary to verify that the tool did not pass a leak defective LT. Therefore, one of the non-leaker LTs had to be damaged so that it could become a leaker that could be used to test out the tool.

The test procedure involved damaging the non-leaking lidthrough using the following set of sequential steps:

1. Pin # 1 was bent 5 times and the LT was leak tested
2. Pin # 1 was bent 7 times and it broke and the LT was leak tested
3. Pin # 2 was bent 5 times and the LT was leak tested
4. Pin # 2 was bent 7 times and it broke and the LT was leak tested
5. Pin # 3 was bent 5 times and the LT was leak tested
6. Pin # 3 was bent 7 times and it broke and the LT was leak tested
7. A 0.060" gauge pin was used to tap on to pin # 2 and # 3 locations and the LT was leak tested
8. A 0.060" gauge pin was used to tap on to pin # 2 and # 3 locations using a 1.75 lb weight and the LT was leak tested
9. The LT was dropped from a height of 4ft above the ground and the LT was leak tested
10. The LT was dropped from a height of 6ft above the ground and the LT was leak tested
11. Antenna (# 4) was bent 5 times and it broke and the LT was leak tested

TEST RESULTS

The results of the lidthrough leak test after each of the steps in the procedure are shown in Table J-1. The results indicate that even after many tests *intended* to damage and crack the Power Module lidthrough, it was observed and recorded that the leak rate was still in the passing range. The above results were reviewed with the CWRU Engineering team and the decision was made to not leak test the PM lidthroughs during incoming inspection at CIRTEC due to their robustness.

TABLE J-1 – POWER MODULE LIDTHROUGH LEAK TESTING

PM1 Lidthrough Leak Testing		
Procedure Step #	Leak Test Results	Pass/ Fail
I	$5.0*10^{-10}$ atm-cc/sec	Pass
II	$5.0*10^{-10}$ atm-cc/sec	Pass
III	$5.0*10^{-10}$ atm-cc/sec	Pass
IV	$5.0*10^{-10}$ atm-cc/sec	Pass
V	$5.0*10^{-10}$ atm-cc/sec	Pass
VI	$5.0*10^{-10}$ atm-cc/sec	Pass
VII	$5.0*10^{-10}$ atm-cc/sec	Pass
VIII	$5.0*10^{-10}$ atm-cc/sec	Pass
IX	$1.8*10^{-9}$ atm-cc/sec	Pass
X	$1.8*10^{-9}$ atm-cc/sec	Pass
XI	$2.8*10^{-9}$ atm-cc/sec	Pass

CONCLUSION

The lidthrough testing revealed that it was not possible to create leaking lidthroughs despite complete damage to the feethrough pins. Therefore, no additional feedthrough testing was performed.

J.3. Power Module and Remote Module Hermeticity Unit Testing

GENERAL DESCRIPTION AND PURPOSE

The Power Module, Pulse Generator Module and Biopotential Module are all designed to be hermetically enclosed titanium cases with hermetic feedthroughs. This document describes the hermetic testing that will be performed *with each subassembly and complete, assembled device*. Modules that do not pass the acceptance criteria will not be used in the final assembly.

TEST CRITERIA

Leak testing is performed according to MIL-STD-883. Standard leak rate is to be less than 2.7×10^{-9} atm-cc/sec helium.

TEST DESIGN AND PROCEDURE

All hermeticity testing is performed per MIL-STD-883.

1. Glass-ceramic feedthrough seals
   The PM1, PG4 and BP2 modules have hermetically sealed glass-ceramic feedthrough seals. These seals are fabricated, inspected, and tested at the vendor (Souriau PA&E, Inc., Wenatchee, WA and Morgan Advanced Ceramics) and are certified to comply to their respective drawing set and subsequent leak-rate criteria.

2. Seam welds
   The PM1, PG4 and BP2 modules have laser-welded seams. The welded seams are visually inspected prior to being hermetically tested as part of the completed device enclosure. The visual inspection criteria for all seam welds are called out on their respective drawing set.

3. Enclosures
   The PM1, PG4 and BP2 module enclosures are welded and sealed in a 75% argon, 25% helium atmosphere to facilitate final leak testing. A Pernicka Model 700H Cumulative Helium Leak Detection (CHLD) System is used for final leak testing. This machine (located at Cirtec Medical) is designed to detect both gross and fine leaks in a single test operation.

J.4. Network Cable Testing

GENERAL DESCRIPTION AND PURPOSE

The Network Cable (NC2) is utilized to conduct power and communication between implanted modules in the NNP System. The NC2 is a critical component of the NNP because all remote modules depend on the proper functioning of the NC2 for power and communication. It is designed to combine features of low electrical resistance with strength and durability. The network cable must conduct the power and communication signal without significant losses and must have excellent fatigue resistance for placement in the extremities where the cable may cross multiple joints. This document describes the endurance testing and electrical characterization of the NC2.

TEST CRITERIA

The test criteria is based on criteria for similar leads (for example PMA P950035) and on the expected bending range, radius and number of cycles that the cable will experience during normal functional use for a minimum of ten years. The specific standards for stretching, crushing, flexing and torsion are as follows:

- Cables shall be functional during and after 1.2×10^6 cycles of stretching to 120% of the initial installed length or separation.
- Cables shall be functional during and after 1.2×10^5 cycles of crushing by a force of 1.2 Newtons delivered over a 1cm x 2mm bar without sharp edges.
- Cables crossing joints or regions of great tissue motion shall be functional during and after 1.2×10^6 cycles of bending (wrapping) over a rod of 3mm radius. The angle of bend (wrap) shall be at least 140º. This is a requirement for flexing life; it is not a requirement for wear or abrasion of the cable against the rod.
- Cables secured to different body tissues shall be functional during and after 6×10^5 cycles of twisting at a rate of 36º of rotation per linear cm of separation about the axis of separation.

In all cases, continuity of the cable is determined by cable resistance measurements at the end of each test condition. Cable failure was defined as an increase in DC resistance of 100% per unit length from initial, pre-test values. In addition, impedance measurements are made for the detection of insulation damage and potential leakage current paths both external to the cable and between individual conductors in the cable. A comparison is made between pre-test and post-test impedance values, with a decrease in impedance of 20% indicating an insulating failure.

TEST DESIGN

All tests were conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator. All tests were conducted under room temperature (nominally, 22 °C) laboratory conditions. Before mechanical testing, each sample was prepared for testing and connected to a Fluke 87III True RMS multimeter to measure electrical resistance with resolution of 0.1Ω. Impedance of the sample was measured using the Electrochemical Impedance Spectroscopy technique. A Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA was utilized to detect damage to the cable insulation layer. Each sample was placed in an electrochemical cell with a test solution of physiological saline solution of 0.9wt% NaCl. An AC voltage of 1V was applied to each filar of the test sample with frequency range varying from 100kHz to 100mHz. Impedance of the cable and phase angle between response current and applied voltage are recorded. The sample is then mounted between two pinvise grips with an exposed sample length of 45mm between the grips.

Mechanical testing was performed on the sample mounted between pinvise grips as follows. Schematic diagrams of each of the test setups is shown in Figure J-1.

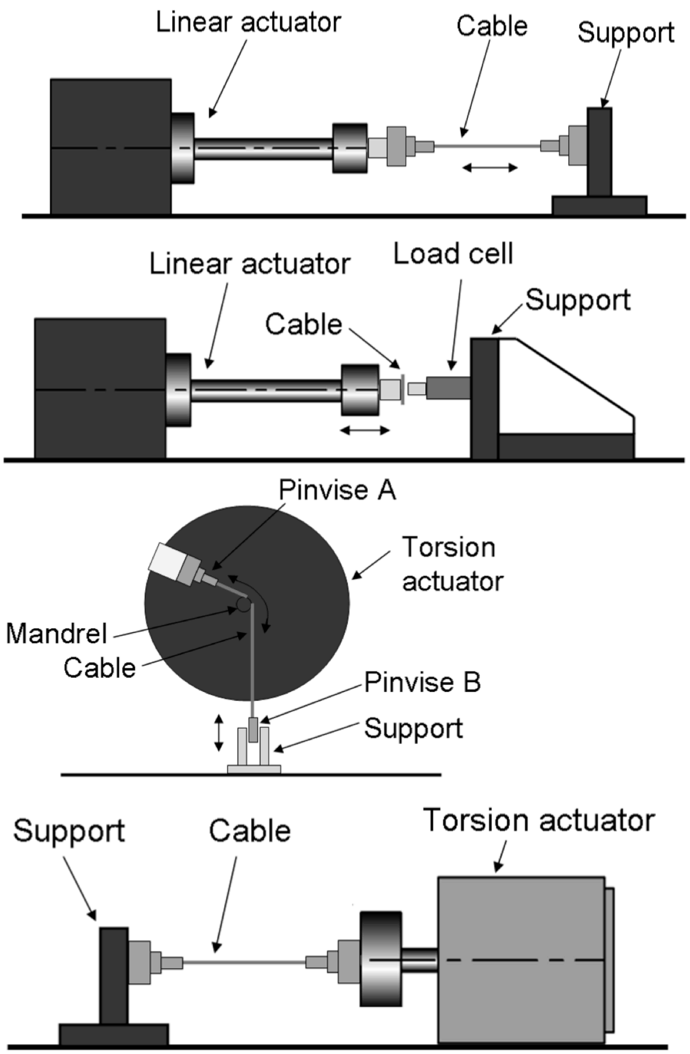

FIGURE J-1. MECHANICAL TEST SETUP SCHEMATIC DIAGRAMS FOR STRETCH (TOP), CRUSH, FLEXION, AND TORSION (BOTTOM) TESTS.

<u>Stretch Test</u>. Apply a static pre-stretch of 2% (i.e. 0.9mm) on the cable using the linear actuator to keep it taut prior to any cyclic stretch testing. Apply a 20% cyclic sinusoidal stretch @ 4Hz for 1.2 million cycles. Monitor the actuator displacement and record actuator displacement vs time data for 10 cycles at the start of the test and after every 100,000 cycles.

<u>Crush Test</u>. Apply 1.2N load crushing force to the cable using the crusher by incrementally pushing the crusher-load cell assembly toward the cable. Monitor the actuator displacement

and load. After 500 cycles, continue to sinusoidally reciprocate the linear actuator for 0.12 million cycles with 5 mm amplitude at 4 Hz. Record the actuator displacement and load data for 10 cycles at the start of the test and after every 20,000 cycles.

Flex Test. Subject the cable to 140° flexion over 6mm diameter mandrel for 1.2 million cycles at 4 Hz. Monitor the actuator rotation and record actuator rotation versus time data for 10 cycles at the start of the test and after every 100,000 cycles.

Torsion Test. Subject the cable to 180 ° cyclic rotation for 0.6 million cycles at 4 Hz in such a way that the torsional load tends to tighten the helically twisted filars. Monitor the actuator displacement and record on the traveler sheet actuator displacement versus time data for 10 cycles at the start of the test and after every 100,000 cycles. Remove the cable with the pinvises and proceed with post-test evaluations.

Leakage Test. An electrochemical impedance spectroscopy technique with a Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA is used, as shown in Figure J-2. Physiological saline solution of 0.9wt% NaCl is used as test solution. A frequency sweep of 100kHz to 100mHz is used to assess potential insulation breakdown. Two frequencies were chosen for a specific pass/fail check: 10kHz and 100kHz.

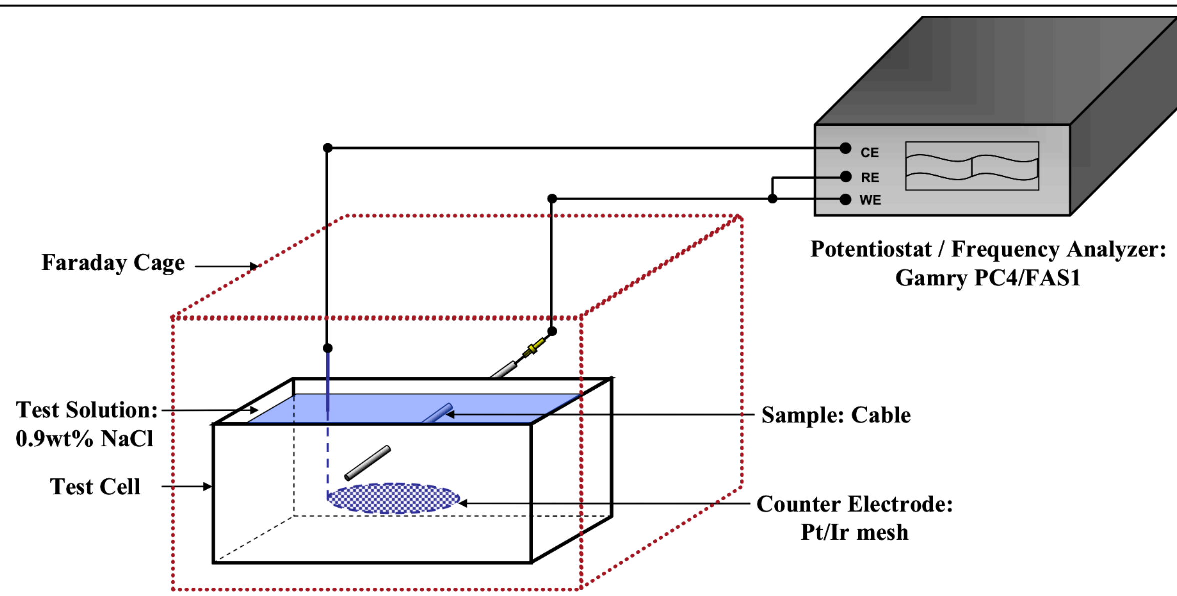

FIGURE J-2. LEAKAGE TESTING USING THE ELECTROCHEMICAL IMPEDANCE SPECTROSCOPY TECHNIQUE.

Final Test. At the completion of the mechanical testing, the electrical resistance and impedance testing is repeated as described above using the multimeter and femtostat. Impedance of the cable and phase angle between response current and applied voltage are recorded. The sample is then bent 90° and the resistance and impedance measurements are repeated. Finally, each cable sample is examined for any damage under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification. Test samples are then stored for inventory.

TEST RESULTS
The results of the mechanical testing are shown in Table J-2. The results of the electrical characterization are shown in Table J-3 Four samples were tested, and all four samples passed. Optical microscope examination did not reveal any evidence of damage to the insulation.

TABLE J-2 – NETWORK CABLE ENDURANCE TESTING – MECHANICAL RESULTS

NC2 Endurance Testing - Mechanical Results

Test	Condition	Cycles	Samples Passed/ Total Samples
Stretching:	$\Delta L/L = 20\%$	1.2×10^6	4/4
Crushing:	F = 100 g/cm	1.2×10^5	4/4
Flexing:	$\Delta\theta = 140^o$, R = 0.3 cm	1.2×10^6	4/4
Twisting:	$\Delta\theta = 180^o$, L = 5 cm	6.0×10^5	4/4

TABLE J-3 – NETWORK CABLE ENDURANCE TESTING – ELECTRICAL RESULTS

New Cable

	Min ohm	Max ohm
DC Resistance per cm	0.028	0.042
Leakage Impedance at 10kHz	2.86×10^6	2.96×10^6
Leakage Impedance at 100kHz	2.73×10^5	2.81×10^5

Tested cable

	Min ohm	Max ohm
DC Resistance per cm	0.031	0.063
90 Bend DC Resistance - Filar	No change	
Leakage Impedance at 10kHz	Pass	
Leakage Impedance at 100kHz	Pass	

CONCLUSION
The Network Cable demonstrates long-term mechanical durability and electrical performance following simulated 10-year conditioning.

J.5. Stainless Steel (SS) Lead Testing

COMPONENT PURPOSE AND DESCRIPTION OF USE

The stimulating and recording electrodes used in the NNP System are based on a 316LVM stranded stainless steel lead. The fundamental design of this lead was based on a percutaneous electrode design utilized in the 1970's through 1990's. For the implanted neuroprostheses developed at the Cleveland FES Center, the multi-strand SS wire was helically wound, forming two parallel conductors, and inserted into a silicone tube to create an extremely flexible and durable lead [Smith, et al., 1987; Akers et al., 1997; Memberg et al., 1994; Kilgore et al., 2003]. A four conductor version of this same multi-strand SS wire was constructed and is utilized with the CWRU spiral nerve cuff electrodes. The SS lead design had been utilized with every Cleveland FES Center implant beginning in 1986. The same lead design was utilized with the Freehand System marketed by NeuroControl Corporation under PMA P950035 from 1997-2001. Thus, significant clinical data exists regarding the durability of this lead design.

MECHANICAL TESTING - TEST CRITERIA

The criteria for the SS lead are identical to the criteria for the Network Cable (NC2). The test criteria is based on criteria for similar leads (for example PMA P950035) and on the expected bending range, radius and number of cycles that the cable will experience during normal functional use for a minimum of ten years. The specific standards for stretching, crushing, flexing and torsion are as follows:

- Cables shall be functional during and after 1.2×10^6 cycles of stretching to 120% of the initial installed length or separation.
- Cables shall be functional during and after 1.2×10^5 cycles of crushing by a force of 1.2 Newtons delivered over a 1cm x 2mm bar without sharp edges.
- Cables crossing joints or regions of great tissue motion shall be functional during and after 1.2×10^6 cycles of bending (wrapping) over a rod of 3mm radius. The angle of bend (wrap) shall be at least 140º. This is a requirement for flexing life; it is not a requirement for wear or abrasion of the cable against the rod.
- Cables secured to different body tissues shall be functional during and after 6×10^5 cycles of twisting at a rate of 36º of rotation per linear cm of separation about the axis of separation.

In all cases, continuity of the cable is determined by cable resistance measurements at the end of each test condition. Cable failure was defined as an increase in DC resistance of 100% per unit length from initial, pre-test values. In addition, impedance measurements are made for the detection of insulation damage and potential leakage current paths both external to the cable and between individual conductors in the cable. A comparison is made between pre-test and post-test impedance values, with a decrease in impedance of 20% indicating an insulating failure.

TEST DESIGN

All tests will be conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator. All tests will be conducted under room temperature (nominally, 22 °C) laboratory conditions. Before mechanical testing, each sample will be prepared for testing and connected to a Fluke 87III True RMS multimeter to measure electrical resistance with resolution of 0.1Ω. Impedance of the sample will be measured using the Electrochemical Impedance Spectroscopy technique. A Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA will be utilized to detect damage to the cable insulation layer. Each sample will be placed in an electrochemical cell with a test solution of physiological saline solution of 0.9wt% NaCl. An AC voltage of 1V will be applied to each filar of the test sample with frequency range varying from 100kHz to 100mHz. Impedance of the cable and phase angle between response current and applied voltage will be recorded. The sample is then mounted between two pinvise grips with an exposed sample length of 45mm between the grips.

Mechanical testing will be performed on the sample mounted between pinvise grips as follows. Schematic diagrams of each of the test setups are shown in Figure J-3, below.

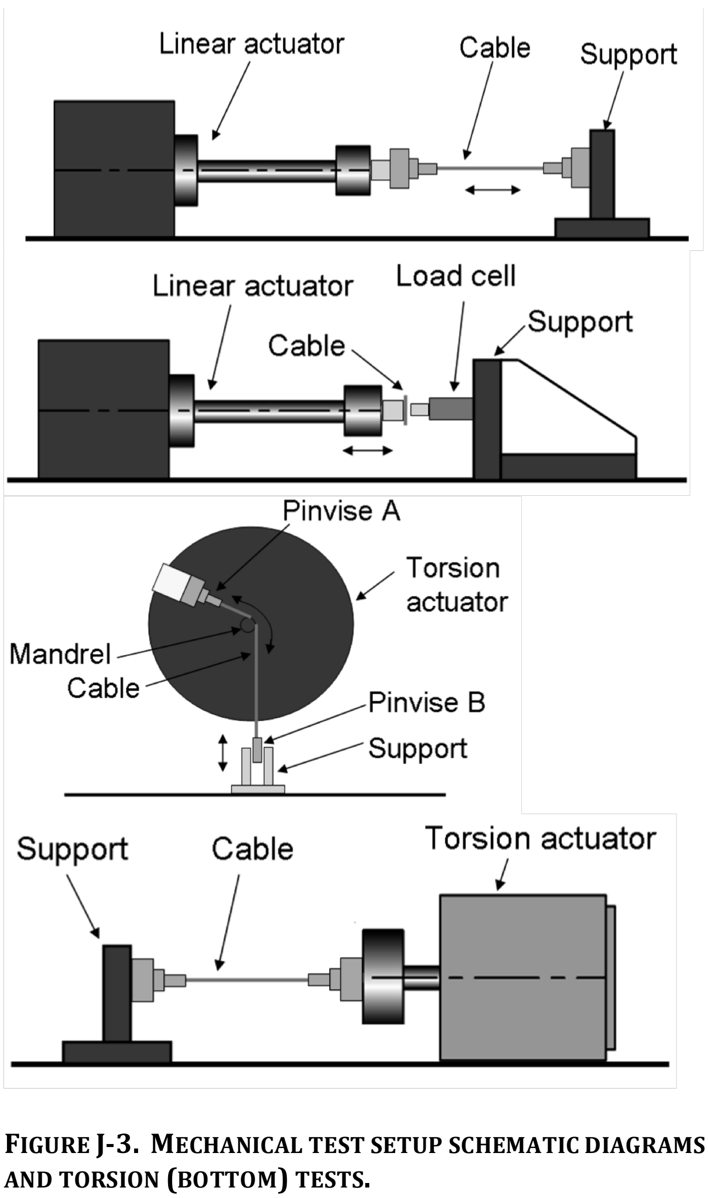

FIGURE J-3. MECHANICAL TEST SETUP SCHEMATIC DIAGRAMS FOR STRETCH (TOP), CRUSH, FLEXION, AND TORSION (BOTTOM) TESTS.

Stretch Test. Apply a static pre-stretch of 2% (i.e. 0.9mm) on the cable using the linear actuator to keep it taut prior to any cyclic stretch testing. Apply a 20% cyclic sinusoidal stretch at 4Hz for 1.2 million cycles. Monitor the actuator displacement and record actuator displacement vs time data for 10 cycles at the start of the test and after every 100,000 cycles.

Crush Test. Apply 1.2N load crushing force to the cable using the crusher by incrementally pushing the crusher-load cell assembly toward the cable. Monitor the actuator displacement and load. After 500 cycles, continue to sinusoidally reciprocate the linear actuator for 0.12 million cycles with 5 mm amplitude at 4 Hz. Record the actuator displacement and load data for 10 cycles at the start of the test and after every 20,000 cycles.

Flex Test. Subject the cable to 140° flexion over 6mm diameter mandrel for 1.2 million cycles at 4 Hz. Monitor the actuator rotation and record actuator rotation versus time data for 10 cycles at the start of the test and after every 100,000 cycles.

Torsion Test. Subject the cable to 180° cyclic rotation for 0.6 million cycles at 4 Hz in such a way that the torsional load tends to tighten the helically twisted filars. Monitor the actuator displacement and record on the traveler sheet actuator displacement versus time data for 10 cycles at the start of the test and after every 100,000 cycles. Remove the cable with the pinvises and proceed with post-test evaluations.

Leakage Test. An electrochemical impedance spectroscopy technique with a Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA will be used, as shown in Figure J-4. Physiological saline solution of 0.9wt% NaCl is used as test solution. A frequency sweep of 100kHz to 100mHz is used to assess potential insulation breakdown. Specific pass/fail check will be performed at 10kHz and 100kHz.

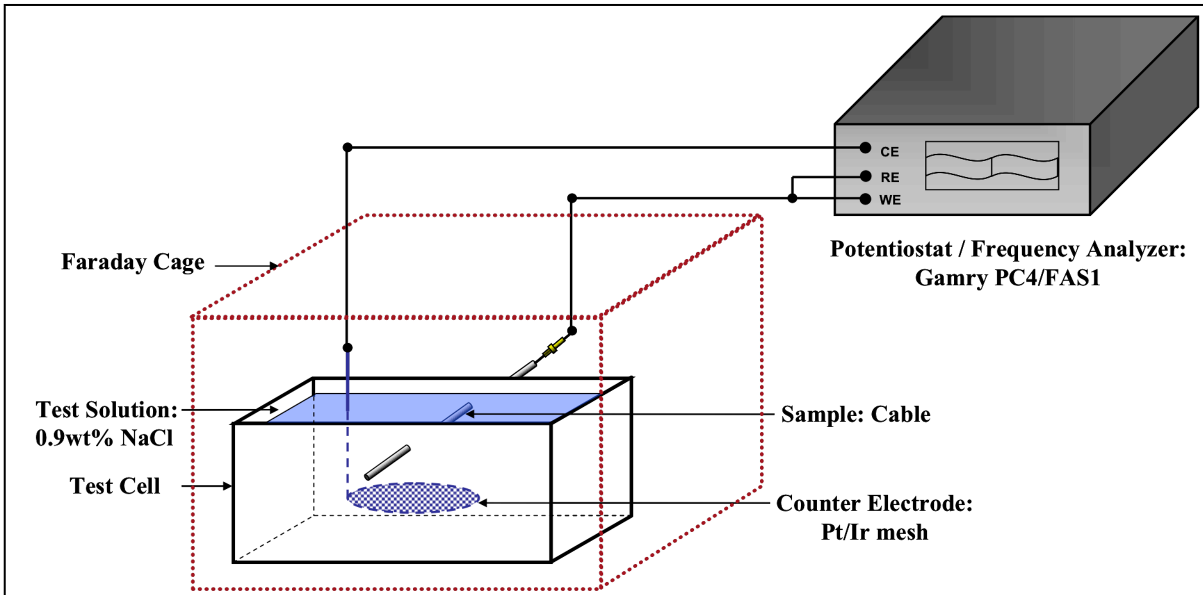

FIGURE J-4. LEAKAGE TESTING USING THE ELECTROCHEMICAL IMPEDANCE SPECTROSCOPY TECHNIQUE.

Final Test. At the completion of the mechanical testing, the electrical resistance and impedance testing is repeated as described above using the multimeter and femtostat. Impedance of the cable and phase angle between response current and applied voltage are recorded. The sample is then bent 90° and the resistance and impedance measurements are repeated. Finally, each cable sample is examined for any damage under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification. Test samples are then stored for inventory.

TEST RESULTS

The results of the mechanical testing of the two-conductor SS lead are shown in Table J-4 and the results of the electrical characterization are shown in Table J-5. Four samples were tested, and all four samples passed. Optical microscope examination did not reveal any evidence of damage to the insulation.

TABLE J-4 – 2-CONDUCTOR SS LEAD ENDURANCE TESTING – MECHANICAL RESULTS

SS2 Endurance Testing - Mechanical Results			
Test	**Condition**	**Cycles**	**Samples Passed/ Total Samples**
Stretching:	$\Delta L/L = 20\%$	1.2×10^6	4/4
Crushing:	F = 100 g/cm	1.2×10^5	4/4
Flexing:	$\Delta\theta = 140°$, R = 0.3 cm	1.2×10^6	4/4
Twisting:	$\Delta\theta = 180°$, L = 5 cm	6.0×10^5	4/4

TABLE J-5 – 2-CONDUCTOR SS LEAD ENDURANCE TESTING – ELECTRICAL RESULTS

New Cable

	Min ohm	Max ohm
DC Resistance per cm	1.92	2.00
Leakage Impedance at 10k	3.00×10^6	3.20×10^6
Leakage Impedance at 100k	2.84×10^5	3.02×10^5

Tested cable

	Min ohm	Max ohm
DC Resistance per cm	1.80	1.84
90 Bend DC Resistance - Filar	No change	
Leakage Impedance at 10k	Pass	
Leakage Impedance at 100k	Pass	

The results of the mechanical testing of the four-conductor SS lead are shown in Table J-6 and the results of the electrical characterization are shown in Table J-7. Ten samples were tested, and nine samples passed all tests. Optical microscope examination did not reveal any evidence of damage to the insulation in these ten samples. In one of the ten samples, three of the four filars failed after being subjected to the complete battery of stretching, crushing, flexing and twisting (the fourth filar had normal impedance). This sample was further analyzed and it was determined that the sample did not fail in fatigue and did not fail in the region contacting the mandril. Therefore, based on the failure analysis of this sample, and the results of the testing with the remaining nine samples, this was determined to be an anomaly due to material or handling defects isolated to this sample.

TABLE J-6 – 4-CONDUCTOR SS LEAD ENDURANCE TESTING – MECHANICAL RESULTS

SS4 Endurance Testing - Mechanical Results			
Test	**Condition**	**Cycles**	**Samples Passed/ Total Samples**
Stretching:	$\Delta L/L = 20\%$	1.2×10^6	9/10
Crushing:	F = 100 g/cm	1.2×10^5	9/10
Flexing:	$\Delta\theta = 140°$, R = 0.3 cm	1.2×10^6	9/10
Twisting:	$\Delta\theta = 180°$, L = 5 cm	6.0×10^5	9/10

TABLE J-7 – 4-CONDUCTOR SS LEAD ENDURANCE TESTING – ELECTRICAL RESULTS

New Cable

	Min ohm	Max ohm
DC Resistance per cm	0.54	0.63
Leakage Impedance at 10k	2.78×10^6	3.43×10^6
Leakage Impedance at 100k	2.65×10^5	3.24×10^5

Tested cable

	Min ohm	Max ohm
DC Resistance per cm	0.53	0.69
90 Bend DC Resistance - Filar	No change	
Leakage Impedance at 10k	Pass	
Leakage Impedance at 100k	Pass	

CONCLUSION

The stainless steel electrode lead demonstrates long-term mechanical durability and electrical performance following simulated 10-year conditioning.