

	Design Verification Protocol – Electrode Cable Post-Test Evaluations	Doc. Number	Rev.
		NNP-DVEP-0010	v1

NNP-DVEP-0010 - Design Verification Protocol – Electrode Cable Post-Test Evaluations

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1.0 Document Purpose

This protocol defines the methods, equipment, acceptance criteria, and procedure for verifying that the Electrode Cable meets the mechanical functional requirements. Information within this protocol has been organized and standardized from the original document, Protocol for Mechanical Qualification Testing of Implantable Cables, seen in Attachment A.

2.0 Document Scope

This protocol addresses verification of the functional requirements that are defined in NNP-REQ-0002 - Product Requirements Specification, Electrode Cable. This test is suitable for the following implantable cables:



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Cable	Part Number
Cable Body, Insulated DFT Filars, Blue/Clear	NNP-DWG-140-012-001
Cable Body, Insulated SS Filars, Red/Clear	NNP-DWG-140-012-002
Cable Body, Insulated SS Filars, Green/Clear	NNP-DWG-140-012-003

Table 1

3.0 Definitions

Terms used in this protocol are defined in the applicable requirements specification(s) and standards, where referenced.

4.0 Requirements Addressed

This protocol addresses the requirement listed below from NNP-REQ-0002 - Product Requirements Specification, Electrode Cable. The Requirement Text is for reference only; the listed Product Requirement Specification document is the definitive source for requirement content.

Req ID	Requirement Text
1.0	Cables must not exhibit an increase in DC resistance greater than 100% per unit length from initial pre-test values.
2.0	Cables must not show a decrease in impedance greater than 20% between pre-test and post-test measurements

5.0 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 0.1W. 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.

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Impedance of the cable and phase angle between response current and applied voltage are recorded. The sample is then mounted between two pin vice grips with an exposed sample length of 45mm between the grips. Stretch, crush, flex, and torsion testing were performed on the sample.

5.1 General Approach

Verification is accomplished using test methods and inspection. Testing is used to confirm the Electrode Cable meets the mechanical requirements. Inspection is used to verify there is no damage or fracture to the insulating tubing of the cable after testing.

5.2 Sample Size

The sample size is four (4) Electrode Cable bodies. The test result is binary (pass/fail) for each test sample. A sample size of 4 was deemed sufficient primarily due to the extensive time required for each test cycle, with hundreds of thousands of cycles needed per sample, each taking a few seconds. This results in several days of continuous testing per sample, meaning that running four samples on a single fixture spans a few weeks. Given the early development phase of the project, limited resources, and budget constraints, it was essential to balance thorough testing with the need to progress on multiple fronts. Contracting external experts in materials science further justified the decision to limit the sample size to four, as the associated costs and the high expense of the testing fixture necessitated a practical approach. Thus, four samples provided adequate data to inform decisions and allow the project to advance efficiently.

5.3 Test Article

The test samples are in a work in progress state; it is the finished cable body before the final assembly with the interconnect and electrodes.

5.4 Test Facility

Verification is conducted in the Case Western Reserve University engineering laboratory under room temperature ($22\pm2^{\circ}\text{C}$) conditions.

5.5 Equipment and Materials

All tests were conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator. After testing, each cable was examined under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification.

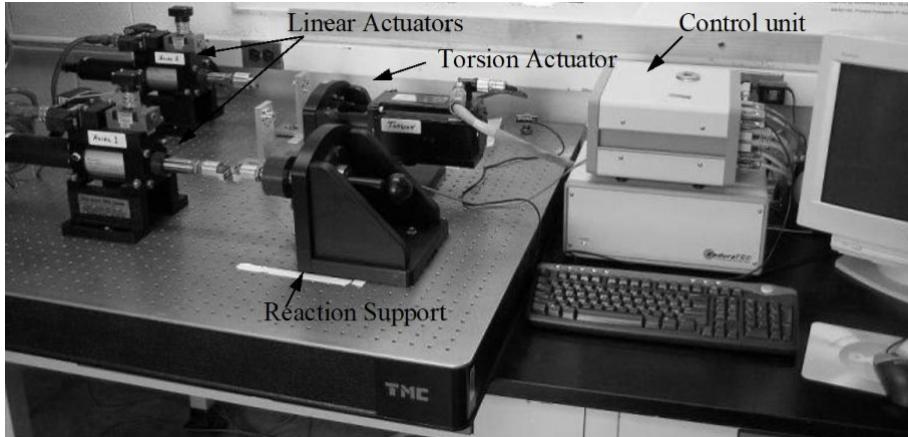


Figure 1 EnduraTEC TestBench with actuators and control unit

5.6 Acceptance Criteria

The acceptance criteria for the mechanical tests are:

- No visual damage or fracture of the cable can be seen through the objective lens of the microscope while moving them slowly.
- The DC resistance per unit length of the cable must not increase by more than 100% from the initial pre-test values. Any cable exceeding this threshold will be considered a failure.
- The impedance of the cable must not decrease by more than 20% between pre-test and post-test measurements. Any cable with an impedance reduction beyond this limit will be deemed to have an insulating failure.

6.0 Procedure

6.1 General

- 6.1.1 All data are recorded on the traveler sheet of Attachment B. Each traveler sheet is dated on the date completed.
- 6.1.2 If the test samples were used for other testing prior to executing this protocol, record a reference to the prior test activities in the Notes section. Document how the test samples were determined to be suitable for use in this protocol.
- 6.1.3 Record anomalies, observations, and comments in the Notes section.

6.2 Specimen Preparation for Post-test Evaluations

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- 6.2.1 Cut off the grip region (i.e. cable inside the pinvises) of the cable on both ends to make a 45mm long specimen.
- 6.2.2 Remove 3mm long outer insulation from both ends of the cables and strip the conductors to expose the wires using hot tweezers.
- 6.2.3 Measure the electrical resistance and impedance of the tested cable as described below.

6.3 Procedure

6.3.1 Electrical Measurement for Resistance

1. The electrical resistance of individual filars and of the whole cable was measured using a Fluke 87III True RMS multimeter with resolution of 0.1Ω .
2. Connect two ends of wire to instrument and measure resistance. Repeat three times.
3. While gently flexing the wire, check for the presence of shorts from wire to wire.
4. Disconnect the wire, proceed to Impedance measurement.

6.3.2 Impedance Measurements for Detection of Wire Damage and Leakage Current

1. Damage in the cable insulation layer will be detected by Electrochemical Impedance Spectroscopy technique with a Gamry PC4/F AS 1 Femtostat with current detection resolution of 1pA . The equipment is controlled by Gamry Instrument Framework software, version 4.35.
2. An electrochemical cell with two electrode configurations will be used as shown in Figure 2. Physiological saline solution of 0.9wt% NaCl is used as test solution.
3. Cut off the stripped out filars at one end so that it can be mounted in the test cell. Crimp the other end of the filars into Cannon pins # 031-9542-001 for electric connection with the external equipment.
4. Mount the specimen in the test cell. Connect the test filar with the equipment. Fill the test cell with test solution.
5. Apply an AC voltage of 1V to the test filar with frequency range varying from 100kHz to 100mHz and data acquisition rate of 10 point/decade. Impedance of the cable and phase angle between response current and applied voltage are recorded.
6. Connect the other filar of the specimen with the equipment and perform the test until the impedance of all filars are measured.

7. Replot the impedance data vs. frequency from 100kHz to 100mHz using Gamry Echem Analyst software, version 1.35. Impedance values at 10kHz and 100kHz are extracted for the traveler sheet.

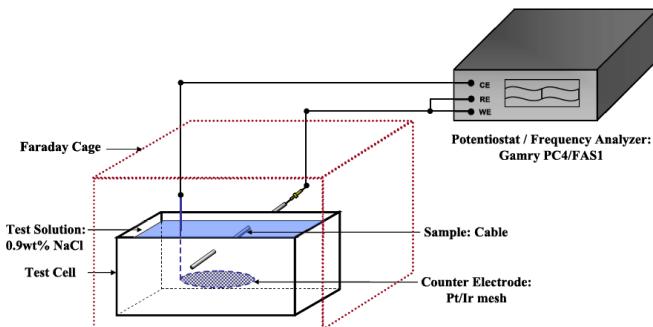


Figure 2 Impedance Measurement Set-Up

6.3.3 Impedance Measurements for the Detection of Inner Insulation Layer Damage and Leakage Current

1. Damage in the inner insulation layer was detected by Electrochemical Impedance Spectroscopy technique with a Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA. The equipment was controlled by Gamry Instrument Framework software, version 4.35.
2. An electrochemical cell with 2 electrode configurations was used as shown in Figure 2. Physiological saline solution of 0.9wt% NaCl was used as test solution.
3. Fill a long glass tube with Vertrel XSi solvent. Completely immerse the specimen in Vertrel and allow the silicon tubing to expand for approximately 5 minutes. Remove the outer silicon tubing.
4. Cut off the crimped end of the specimen so that all filars are isolated from each other. Crimp the other end of each filars into a Cannon pin # 031-9542-001 for electric connection with the external equipment.
5. Mount the specimen in the test cell. Connect the test filar with the equipment. Fill the test cell with test solution.
6. Apply an AC voltage of 1 V to the test filar with frequency range varying from 100kHz to 100mHz and data acquisition rate of 10 point/decade. Impedance of the cable and phase angle between response current and applied voltage were recorded.

7. Connect the other filar of the specimen with the equipment and perform the test until impedance of all filars are measured.
8. Replot the impedance data vs. frequency from 100kHz to 100mHz using Gamry Echem Analyst software, version 1.35. Impedance values at 1Hz and 1kHz were extracted for traveler sheet report.

6.3.4 Electrical Measurement for Resistance during Bending an Angle of 90° on Different Directions

1. The electrical resistance of individual filars was measured using a Fluke 87III True RMS multimeter with resolution of 0.1Ω .
2. The cables were fixed inside a hole by a mechanism as shown in Figure 3 so that the middle part of the cables, which was under the maximum stresses during mechanical test, was exposed.
3. Bend the cable 90° on the Up direction as shown in Figure 3. Connect two ends of each filar to instrument and measure resistance.
4. Repeat step 3 with the other bending directions.

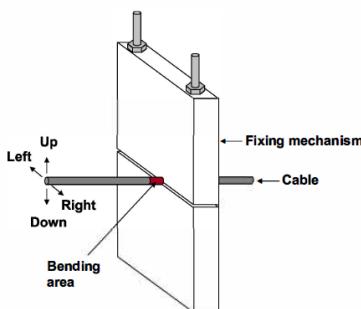


Figure 3 Resistance Measurement Set-Up

6.3.5 Optical Examination

1. After electrical measurements each cable was examined under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification.
2. All the cables were examined for any damage or fracture by placing them below the objective lens of the microscope and moving them slowly.

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6.3.6 Return the Specimen to Storage

1. Remove the specimen from the test cell.
2. Clean the specimen with water then dry in air for 10 minutes.
3. Transfer the specimen to specimen inventory.

7.0 Attachments

Attachment A: PRJ-NNPS-TST-PLN-07_B Cable Endurance Testing

Attachment B: PRJ-NNPS-TST-TR-01 Traveler, Cable, Mechanical Qualification Testing

8.0 References

Number	Title
PRJ-NNPS-TST-PLN-07_B	Cable Endurance Testing
NNP-REQ-0002	Product Requirements Specification, Electrode Cable
PRJ-NNPS-TST-TR-01	Traveler, Cable, Mechanical Qualification Testing

9.0 Revision History

Revision	Summary of Changes	Date	Author
v1	Document implementation for origination of QMS	1/22/2024	E. Linder

10.0 Approvals

See Document Change Request log for approvals.



Attachment A

Protocol for Mechanical Qualification Testing of Implantable Cables



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2. PURPOSE

To evaluate the mechanical durability of implantable cables by performing a series of accelerated tests.

3. SCOPE

This test plan is suitable for testing the following implantable cables:

Cable	Part Number
DFT, 4 filar	03-30-0510
DFT, 2 filar	03-30-0210
316SS, 4 filar	03-30-0410
316SS, 2 filar	03-30-0110

Table 1

4. DEFINITIONS

Cable: an assembly of individually insulated filars twisted together.

Filar: an individual insulated conductor in a cable.

Strand: a group of wires twisted together.

Wire: the individual elements making up a strand.

5. REFERENCES

PRJ-NNPS-TST-TR-01 Traveler, Cable, Mechanical Qualification Testing

6. TEST EQUIPMENT

All tests were conducted using EnduraTEC TestBench (Bose Corporation, Minnetonka, MN) equipped with two pneumatic linear actuators and one electromagnetic torsion actuator

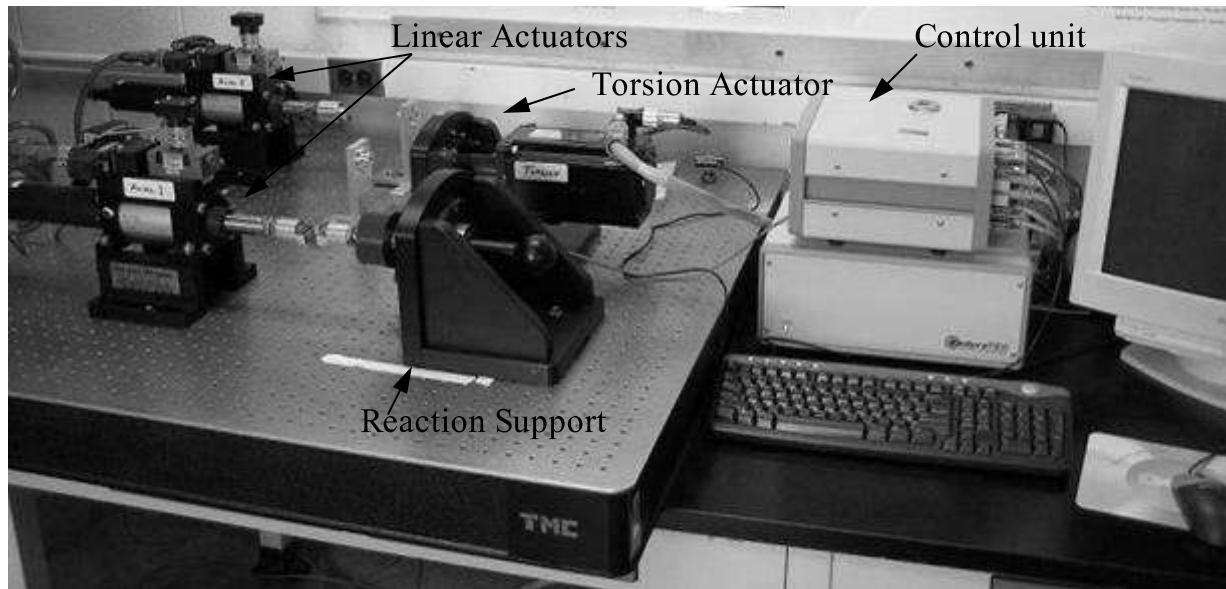


Figure 1 EnduraTEC TestBench with actuators and control unit

7. GENERAL TEST CONDITIONS

All tests were conducted under room temperature ($22 \pm 2^\circ\text{C}$) laboratory conditions.

8. MECHANICAL TEST PROCEDURES

8.1. Pre-Test Sample Preparation

1. Remove sample material from inventory.
2. Take a 71 mm long cable from Table 1.
3. Remove 3mm long outer insulation on both ends of the cable and strip the conductors to expose the wires using hot tweezers.
4. Measure the electrical resistance of the cable and impedance as described in Sections 9.2 and 9.3.
5. Record result on Traveler Sheet.

8.2. Mount specimen in test grips

1. Cut off the stripped out filars (The cable is now 65 mm long).
2. Mark the grip region (10 mm from both ends of the cable).
3. Grip each end of the cable (finger tight) using a pinvise on each end so that the gage length between the pinvises is 45 mm (Figure 2). The gage length is defined as the cable length between the two pinvises.
4. Calibrate the actuators and the load cell before testing each specimen

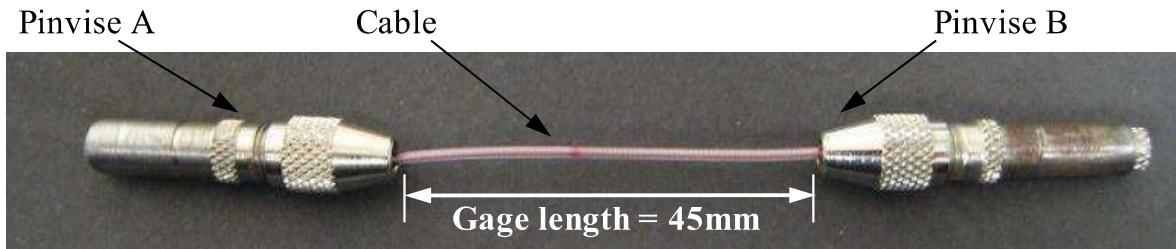


Figure 2 Cable with pinvises. Pinvises are finger tightened to hold the cable.

8.3. Stretch test

1. Performed using Pneumatic linear actuator (Figure 3a).
2. The cable with the pinvises is fixed as shown in Figure 3b.
3. Apply a static pre-stretch of 2% (ie. 0.9mm) on the cable using the linear actuator to keep it taut prior to any cyclic stretch testing.
4. Apply a 20% cyclic sinusoidal stretch @ 4Hz for 1.2 million cycles. Figure 4 shows the typical sinusoidal loading waveform.
5. 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.
6. Remove the cable with the pinvises attached, record the gage length on the traveler sheet, and proceed with the crush test.

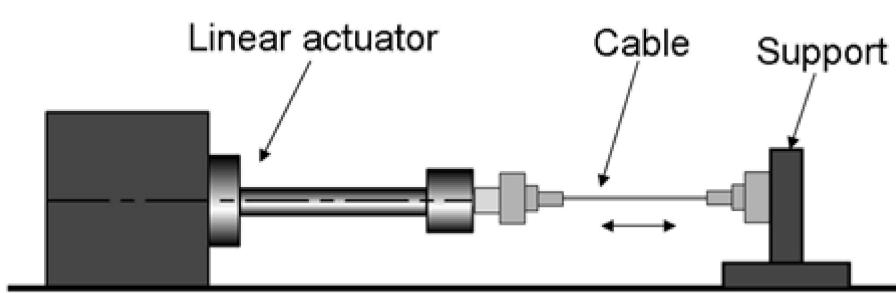


Figure 3a Stretch Test - Schematic



Figure 3b Stretch Test – Setup



Figure 4 Stretch Test - Loading

8.4. Crush test

1. Performed using Pneumatic linear actuator (Figure 5a).
2. Attach the cable with the pinvises (which has been subjected to stretch test, 8.3) to the linear actuator as shown in Figure 5b.
3. Let the linear actuator reciprocate sinusoidally for 500 cycles with 5mm peak-to-peak amplitude at 4 Hz with no load on the cable.
4. Apply 1.2N load crushing force to the cable using the crusher by incrementally pushing the crusher-load cell assembly toward the cable (Figure 6).

5. 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.
6. Record the actuator displacement and load data for 10 cycles at the start of the test and after every 20,000 cycles.
7. Remove the cable with the pinvises, record the gage length on the traveler sheet, and proceed with the flex test.

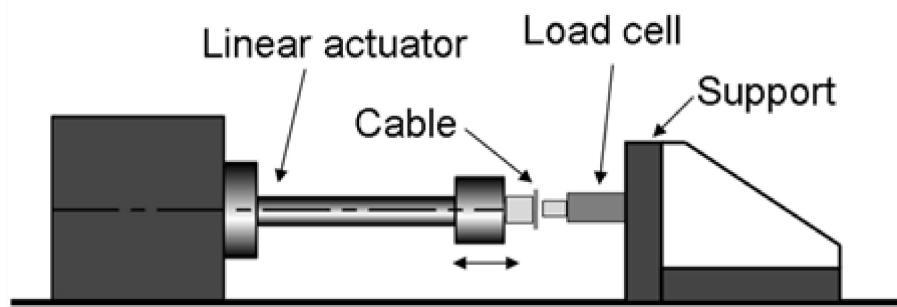


Figure 5a Crush Test - Schematic



Figure 5b Crush Test – Specimen Setup

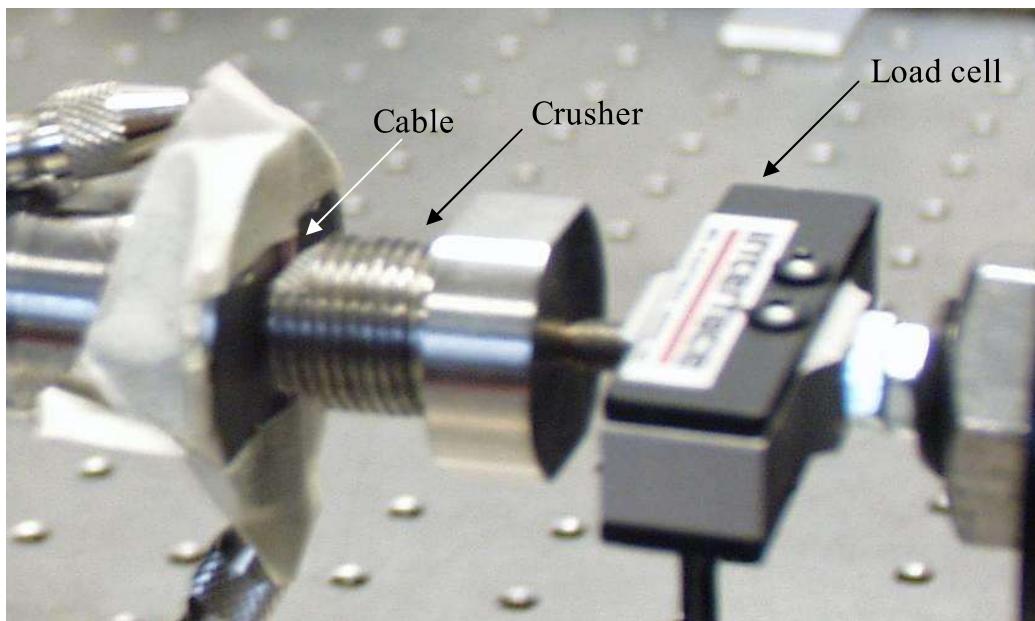


Figure 6 Crush Test – Setup

Note: Although the relative displacement of the test surfaces follows a sinusoid, the magnitude of the crush force applied will not.

8.5. Flex test

1. Performed using Electromagnetic torque actuator.
2. Attach the cable with the pinvises (which has been subjected to crush test, 8.4) to the flex fixtures as shown in Figure 7.
3. Pinvise A is fixed and pinvise B slides inside a hollow support.
4. Subject the cable to 140° flexion over 6mm diameter mandrel for 1.2 million cycles at 4 Hz.
5. Monitor the actuator rotation and record actuator rotation vs time data for 10 cycles at the start of the test and after every 100,000 cycles.
6. Remove the cable with the pinvises, record the gage length on the traveler sheet, and proceed with the torsion test.



Figure 7a Flex Test – Schematic



Figure 7b Flex Test – Setup

8.6. Torsion test

1. Performed using Electromagnetic torsion actuator (Figure 8a).
2. Attach the cable with the pinvises (which has been subjected to flex test, 8.5) to the torsion fixtures as shown in Figure 8b in such a way that there is 2% pre-stretch to the gage length. Note that the current gage length may be slightly larger than the starting (i.e. 45 mm) gage length.

3. 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 (remember to check the direction of the wire strand lay).
4. 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.
5. Remove the cable with the pinvises and proceed with post-test evaluations.

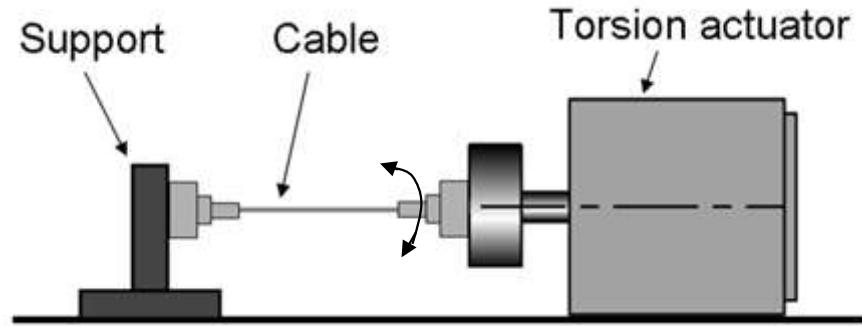


Figure 8a Torsion Test – Schematic

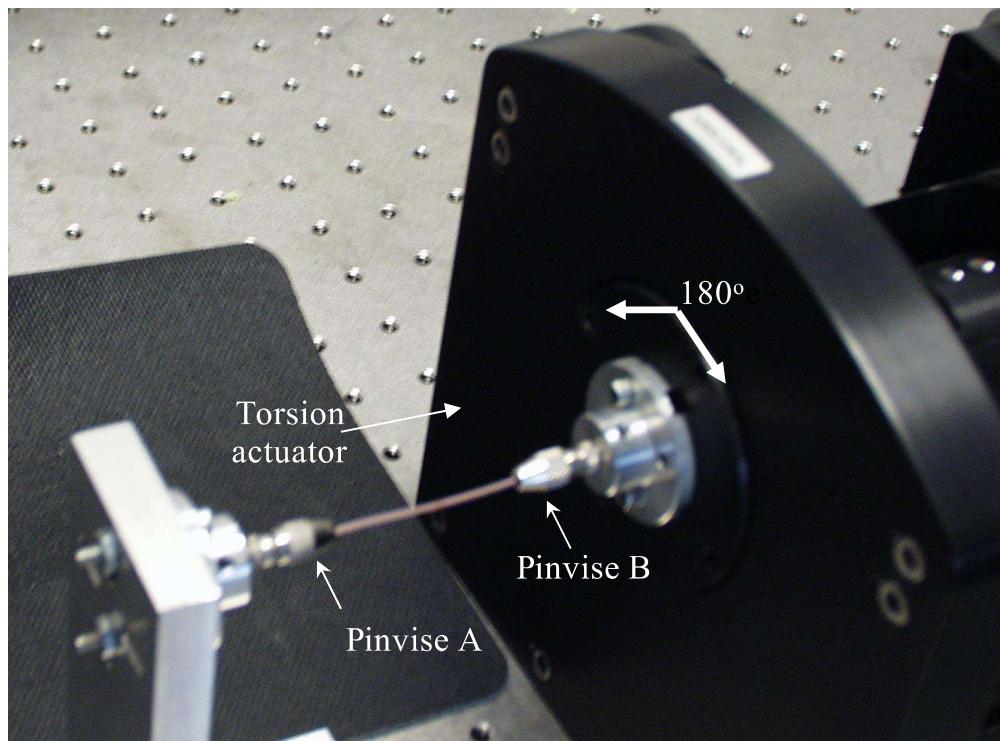


Figure 8b Torsion Test - Setup

9. POST-TEST EVALUATIONS

9.1. Specimen Preparation for Post-test Evaluations

1. Cut off the grip region (i.e. cable inside the pinvises) of the cable on both ends to make a 45mm long specimen.
2. Remove 3mm long outer insulation from both ends of the cables and strip the conductors to expose the wires using hot tweezers.
3. Measure the electrical resistance and impedance of the tested cable as described below.

9.2. Electrical Measurement for Resistance

1. The electrical resistance of individual filars and of the whole cable was measured using a Fluke 87III True RMS multimeter with resolution of 0.1Ω .
2. Connect two ends of wire to instrument and measure resistance. Repeat three times.
3. While gently flexing the wire, check for the presence of shorts from wire to wire.
4. Disconnect the wire, proceed to Impedance measurement.

9.3. Impedance Measurements for detection of Wire Damage and Leakage Current

1. Damage in the cable insulation layer will be detected by Electrochemical Impedance Spectroscopy technique with a Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA. The equipment is controlled by Gamry Instrument Framework software, version 4.35.
2. An electrochemical cell with two electrode configuration will be used. Physiological saline solution of 0.9wt% NaCl is used as test solution.
3. Cut off the stripped out filars at one end so that it can be mounted in the test cell. Crimp the other end of the filars into Cannon pins # 031-9542-001 for electric connection with the external equipment.
4. Mount the specimen in the test cell. Connect the test filar with the equipment. Fill the test cell with test solution.
5. Apply an AC voltage of 1V to the test filar with frequency range varying from 100kHz to 100mHz and data acquisition rate of 10 point/decade. Impedance of the cable and phase angle between response current and applied voltage are recorded.
6. Connect the other filar of the specimen with the equipment and perform the test until the impedance of all filars are measured.
7. Replot the impedance data vs. frequency from 100kHz to 100mHz using Gamry Echem Analyst software, version 1.35. Impedance values at 10kHz and 100kHz are extracted for the traveler sheet.



Figure 9 Impedance measurement setup

9.4. Impedance Measurements for the Detection of Inner Insulation Layer Damage and Leakage Current

1. Damage in the inner insulation layer was detected by Electrochemical Impedance Spectroscopy technique with a Gamry PC4/FAS1 Femtostat with current detection resolution of 1pA. The equipment was controlled by Gamry Instrument Framework software, version 4.35.
2. An electrochemical cell with 2 electrode configuration was used as shown in Figure 9. Physiological saline solution of 0.9wt% NaCl was used as test solution.
3. Fill a long glass tube with Vertrel XSi solvent. Completely immerse the specimen in Vertrel and allow the silicon tubing to expand for approximately 5 minutes. Remove the outer silicon tubing.
4. Cut off the crimped end of the specimen so that all filars are isolated from each other. Crimp the other end of each filars into a Cannon pin # 031-9542-001 for electric connection with the external equipment.
5. Mount the specimen in the test cell. Connect the test filar with the equipment. Fill the test cell with test solution.
6. Apply an AC voltage of 1V to the test filar with frequency range varying from 100kHz to 100mHz and data acquisition rate of 10 point/decade. Impedance of the cable and phase angle between response current and applied voltage were recorded.
7. Connect the other filar of the specimen with the equipment and perform the test until impedance of all filars are measured.
8. Replot the impedance data vs. frequency from 100kHz to 100mHz using Gamry Echem Analyst software, version 1.35. Impedance values at 1Hz and 1kHz were extracted for traveler sheet report.

9.5. Electrical Measurement for Resistance during Bending an Angle of 90° on Different Directions

1. The electrical resistance of individual filars was measured using a Fluke 87III True RMS multimeter with resolution of 0.1Ω .
2. The cables were fixed inside a hole by a mechanism as shown in Figure 10 so that the middle part of the cables which was under the maximum stresses during mechanical test was exposed.
3. Bend the cable 90° on the Up direction as shown in Figure 10. Connect two ends of each filar to instrument and measure resistance.
4. Repeat step 3 with the other bending directions.

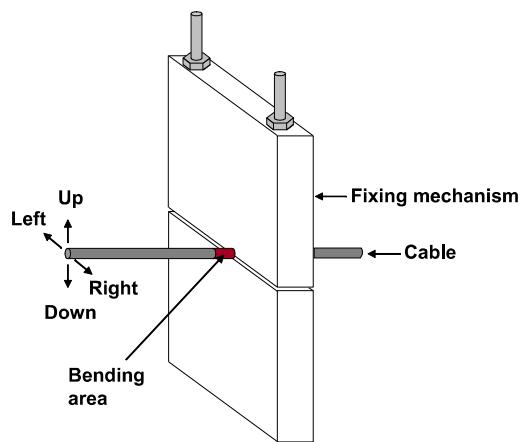


Figure 10. Resistance measurement set-up

9.6. Optical Examination

1. After electrical measurements each cable was examined under an Olympus DP20 (Olympus America Inc, Center Valley, PA) optical microscope at 45x magnification.
2. All the cables were examined for any damage or fracture by placing them below the objective lens of the microscope and moving them slowly.

9.7. Return the specimen to storage

3. Remove the specimen from the test cell.
4. Clean the specimen with water then dry in air for 10 minutes.
5. Transfer the specimen to specimen inventory.

10. REVISION HISTORY

REV	DESCRIPTION	AUTHOR	DATE	APPROVAL
A	Initial draft	RV/HH	5/28/08	
B	New Sections 9.5 and 9.6 inserted	RV/HH	5/1/09	



Attachment B

Traveler Sheet for Cable Endurance Tests



Development of Networked Implantable Neuroprostheses (NNPS)

Traveler sheet for Cable Endurance Tests

SPECIMEN ID: _____

Cable: _____ Supplied by: _____ Serial No: _____ Part No: _____ Rev: _____

Protocol: _____

1. Pre-Test Evaluations

Date: ____ / ____ / ____ Cable length: ____ mm, Initials: _____

Data Acquisition: scan from 100kHz to 100mHz, record rate 10point/decade

Cable Resistance: min ____ Ω max ____ Ω, Impedance 10kHz _____, Impedance 100kHz _____;

Data File _____

Notes: Resistance value reported from 3 different measurements.

2. Stretch Test (Test Parameters: 2% Pre stretch, 20% Stretch, 4Hz, 1.2 million cycles)

Start Date: ____ / ____ / ____ Gage length (Start): ____ mm, End Date: ____ / ____ / ____ Gage length (End): ____ mm,
Initials: _____

Data Acquisition: 10 cycles data for every 100,000 cycles;

Data File _____

Notes:

3. Crush Test (Test Parameters: 1.2N Crush, 4Hz, 0.12 million cycles)

Start Date: ____ / ____ / ____ Gage length (Start): ____ mm, End Date: ____ / ____ / ____ Gage length (End): ____ mm,
Initials: _____

Data Acquisition: 10 cycles data for every 20,000 cycles;

Data File _____

Notes:

4. Flex Test (Test Parameters: 140° Flex, 4Hz, 1.2 million cycles)

Start Date: ____ / ____ / ____ Gage length (Start): ____ mm, End Date: ____ / ____ / ____ Gage length (End): ____ mm,

Initials: _____

Data Acquisition: 10 cycles data for every 100,000 cycles;

Data File _____

Notes:

5. Torsion Test (Test Parameters: 2% Pre stretch, 180° Twist, 4Hz, 0.6 million cycles)

Start Date: ____ / ____ / ____ Gage length (Start): ____ mm, End Date: ____ / ____ / ____ Gage length (End): ____ mm,

Initials: _____

Data Acquisition: 10 cycles data for every 100,000 cycles;

Data File _____

Notes:

6. Post-Test Evaluations

Date: ____ / ____ / ____ Cable length: ____ mm, Initials: _____

Data Acquisition: scan from 100kHz to 100mHz, record rate 10point/decade

Cable Resistance: min ____ Ω max ____ Ω, Impedance 10kHz ____ Ω Impedance 100kHz ____ Ω;

Data File _____

Filar: ____ Resistance: min ____ Ω max ____ Ω, Impedance 10kHz ____ , Impedance 100kHz ____ ;

Data File _____

Filar: ____ Resistance: min ____ Ω max ____ Ω, Impedance 10kHz ____ , Impedance 100kHz ____ ;

Data File _____

Filar: ____ Resistance: min ____ Ω max ____ Ω, Impedance 10kHz ____ , Impedance 100kHz ____ ;

Data File _____

Filar: ____ Resistance: min ____ Ω max ____ Ω, Impedance 10kHz ____ , Impedance 100kHz ____ ;

Data File _____

Notes: Resistance values reported from 3 different measurements.

7. Revision History

REV	DESCRIPTION	AUTHOR	DATE	APPROVAL
A	Initial draft	RV/HH	6/9/08	