

	Design Verification Report - Network Cable Torsion Test	Doc. Number	Rev.
		NNP-DVER-0004	v1

NNP-DVER-0004 - Design Verification Report – Network Cable Flex Test

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1.0 Document Purpose

This report documents design verification of the COSMIIC system against its functional requirements. This verification activity was conducted in accordance with NNP-DEVP-0004 – Design Verification Protocol - Network Cable Torsion Test.

2.0 Document Scope

This report addresses verification of the COSMIIC system against the functional requirements that are defined in NNP-REQ-0001 – Product Requirements Specification – Network Cable.

This includes the following cables:

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

3.0 Background

Initial design verification of the network cables against its functional requirements was conducted to verify against NNP-REQ-0001 for the IDE submission of the COSMIIC device.

4.0 Definitions

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

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5.0 Requirements Addressed

This protocol addresses the requirement listed below from NNP-REQ-001 – Product Requirements Specification – Network 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 secured to different body tissues shall be functional during and after 6×10^5 cycles of twisting at a rate of 36° of rotation per linear cm of separation about the axis of separation.

6.0 Verification by Analysis

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 8711 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. Impedance of the cable and phase angle between response current and applied voltage were recorded. The sample was then mounted between two pinvis grips with an exposed sample length of 45mm between the grips.

Torsion testing was performed on the sample mounted between pinvis grips as follows. A schematic diagram for this test setup is shown in Figure 1.

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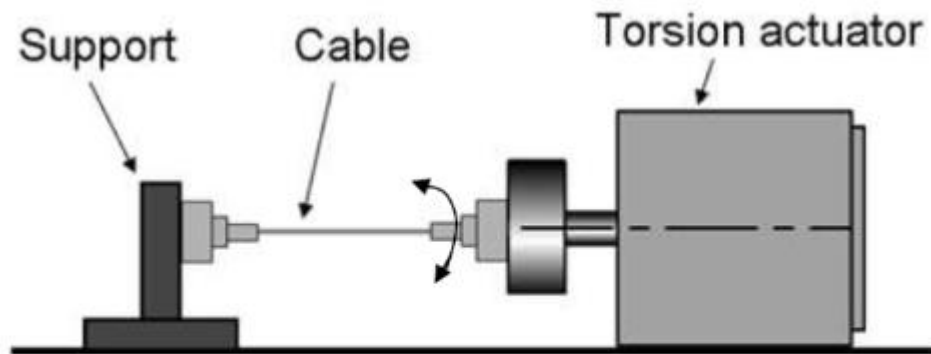


Figure 1 Torsion Test - Schematic

Figure 1. Torsion Test - Schematic

6.1 General Approach

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

6.2 Sample Size

The sample size was four (4) Network Cable bodies. The test result was 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 resulted in several days of continuous testing per sample, meaning that running four samples on a single fixture spanned 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.

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6.3 Test Article

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

6.4 Test Facility, Dates and Personnel

Verification was conducted in the Case Western Reserve University engineering laboratory under room temperature ($22\pm 2^{\circ}\text{C}$) conditions.

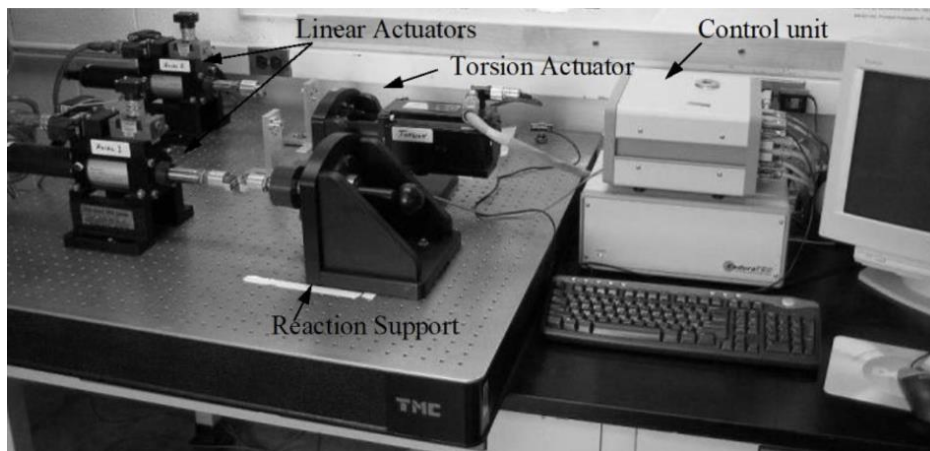


Figure 2. EnduraTEC TestBench with actuators and control unit.

6.5 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.

6.6 Acceptance Criteria

The acceptance criterion for the mechanical flex test was:

- No visual damage or fracture of the cable can be seen through the objective lens of the microscope while moving them slowly.

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7.0 Deviations

There were no deviations to the protocol.

8.0 Test Results

Sample ID	Sample Type	Visual Inspection Pass/Fail	Notes
50-1	316LVM, 2-filar	NA	Apparatus failed, test invalid
50-2		Pass	
50-3		Pass	
50-4		Pass	
50-5		Pass	
52-1	DFT, 2-filar	Pass	
52-2		Pass	
52-3		Pass	
52-4		Pass	
53-1	DFT, 4-filar	Pass	
53-2		Pass	
53-3		Pass	
53-4		Pass	

For the 316LVM 2-filar sample type, one test iteration experienced an apparatus failure and thus an additional sample was tested. All additional 4 test samples passed testing.

For the DFT 2-filar sample type, all samples passed testing.

For the DFT 4-filar sample type, all samples passed testing.

9.0 Conclusion

All samples that did not experience apparatus failure passed the visual inspection acceptance criteria required in this protocol.

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The COSMIIC system components, part numbers NNP-DWG-140-012-001, NNP-DWG-140-012-002, and NNP-DWG-140-012-003, successfully satisfied the functional requirements (REQ ID 1.0) defined in NNP-REQ-0001 - Product Requirements Specification – Network Cable.

10.0 References

Document Identifier	Title
NNP-DVEP-0003	Design Verification Protocol – Network Cable Flex Test
NNP-REQ-0001	Product Requirements Specification – Network Cable
NNP-DWG-140-012-001	Cable Body, Insulated DFT Filars, Blue/Clear
NNP-DWG-140-012-002	Cable Body, Insulated SS Filars, Red/Clear
NNP-DWG-140-012-003	Cable Body, Insulated SS Filars, Green/Clear

11.0 Revision History

Revision	Summary of Changes	Date	Author
v1	First version of document.	7/15/2024	J. Daghestani

12.0 Approvals

See Document Change Request log for approvals.