

	Product Requirements Specification - Network Cable	Doc. Number	Rev.
		NNP-REQ-0001	v1

NNP-REQ-0001 - Product Requirements Specification - Network Cable

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1.0 Document Purpose

This document defines the requirements that establish the suitability of the Network Cable within the COSMIIC System. Requirements are established for the functional characteristics, electrical characteristics, physical connectivity characteristics, and reliability longevity.


2.0 Document Scope

This document is an engineering specification that defines particular product requirements associated with the Network Cable of the COSMIIC system. The requirements defined in this document were used as input to the design process and as a basis for verification testing.

3.0 Background and Categorization

3.1 Background

The Network Cable is a component of the COSMIIC System, an Active Implantable Medical Device (AIMD) that restores muscular function for spinal cord injury patients. There are two types of cables: a lead cable and a network cable. The Network Cable is the mechanism for interconnecting modules with power and communication. Although both have similar designs at the interconnect, the cables are designed and fabricated differently.

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The network cable is a four-filar, two-conductor cable helically wound and electrically connected to each of the connector's contact surfaces. Each filar is composed of seven strands of drawn-filled tube (DFT) wire. The DFT wire is a tube of MP35N with a core of silver. The network cable is utilized to conduct power and communication between implanted modules in the COSMIIC System. Power on the cable is provided by connection to the power module and network communication can be generated by any module. Every remote module must be connected to the network through a network cable. The cable is terminated at each end with an identical male connector; strain relief is provided at each end of the cable for durability and to provide stiffness for insertion into each module.

3.2 Functional Requirements Specification

Technical specifications of the Network Cable, described in Sections 5.0 and on, are developed to meet the Functional Specifications herein—qualitative outcomes that will be achieved by the successful implementation of the technical specifications, however, are not directly tested upon in the Verification process.

Requirement NC.3.2.1: Reversible connectivity

The Network Cable shall provide reversible connectivity between modules.

Requirement NC.3.2.2: Flexibility through joint motions

The Network Cable shall be flexible, pliable, and extensible enough to user muscle, tissue, or joint motions transmitting excessive torque through the cables to the implanted components.

Requirement NC.3.2.4: Decade durability

The Network Cable shall be durable for human use with at least 10 year expected lifetime.

Requirement NC.3.2.5: Functionality after mechanical motions

The Network Cable shall remain functional during and after exposure to the mechanical motions of the limbs.

Requirement NC.3.2.6: Surgical replacement

The Network Cable shall allow for ease of replacement in surgical operations.

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Requirement NC.3.2.7: Power transmission

The Network Cable shall carry power safely using an alternating current signal.

4.0 Technical Requirement Specification

Sections 5 through 7 address technical requirements for the design development and verification of the Network Cable. Each requirement is assigned a unique identifier that will never be changed. Requirements may be added or deleted with document revisions but the assigned identifiers are not re-used.

5.0 Electrical Requirements

Requirement NC.5.1: Isolation of electrical conductors

The Network Cable shall have two isolated electrical conductors.

Requirement NC.5.2: Network transmission rate

The Network Cable shall allow a network transmission rate greater than 100 kilobits/sec.

Requirement NC.5.3: Lead resistance

The Network Cable shall have a lead resistance less than 0.1 ohms/cm.

Requirement NC.5.4: Electrical leakage

The Network Cable shall have electrical leakage at the interconnect less than 1 microAmp.


6.0 Connection Requirements

Requirement NC.6.1: Plug-in connector

The Network Cable shall have two identical two-conductor plug-in connectors on each end of the cable.

Requirement NC.6.2: Disconnection without destruction

The Network Cable shall disconnect without destruction of the cable or module(s) to which it is connected.

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Requirement NC.6.3: No use of sutures

The Network Cable must not require the use of sutures for interconnection of modules nor surgical placement.

7.0 Reliability Requirements

Requirement NC.7.1: Functionality across stretching

The Network Cable shall remain functional during and after 1.2×10^6 cycles of stretching to 120% of the initial installed length or separation.

Requirement NC.7.2: Functionality across crushing

The Network Cable shall remain 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.

Requirement NC.7.3: Functionality across bending

The Network Cable shall remain functional during and after 1.2×10^6 cycles of bending (wrapping) over a rod of 3mm radius with an angle of bend (wrap) of at least 140°.

Requirement NC.7.4: Functionality across twisting

The Network Cable shall remain 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.

8.0 Reference Information

8.1 Standards

Not applicable

8.2 Related Documents

Not applicable

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8.3 Definitions

Term	Definition
AIMD	Active Implantable Medical Device
DFT	Drawn-Filled Tube

9.0 Revision History

Revision	Summary of Changes	Date	Author
v1	Document implementation for open source release	6/21/2024	C. Rexroth