NNP-REQ-0002 - Product Requirements Specification - Electrodes

Contents

1.0 Document Purpose

This document defines the requirements that establish the suitability of the Electrodes 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 Electrodes 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 Electrodes are components of the COSMIIC System, an Active Implantable Medical Device (AIMD) that restores muscular function for spinal cord injury patients. Electrodes, as referred to in this document, represent the entirety of connector, cable, and tissue-contacting lead. There are two possible lead connections, an Intramuscular Stimulating Electrode or Epimysial Stimulating Electrode. This document does not provide a requirements specification for these designs as they are considered validated through the historical use across multiple IDEs and

the Freehand System marketed by NeuroControl Corporation under PMA P950035 from 1997-2001. The connector and cable of the Electrodes share many of the same functional and technical requirements as the Network Cable.

The electrode cable is fabricated using wires of 316LVM stainless steel (0.034 mm diameter each), organized into a single seven-filament strand and coated with a perfluoroalkoxy polymer (PFA) to form an insulated, conducting filar. The cable is fabricated by winding two filars in tandem, forming a double helix of two conductors electrically insulated along their length. The coiled filars are placed inside medical-grade silicone tubing to form the cable. The cable outer diameter is approximately 1.3 mm.

3.2 Functional Requirements Specification

Technical specifications of the Electrodes, described in Sections 5.0 and on, are developed to meet the functional requirements 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. The functional requirements for the connector and cable of the Electrodes are a subset of those described for the Network Cable, described in Section 3.2 of *NNP-REQ-0001 – Product Requirements Specification – Network Cable.*

Requirement EL.3.2.1: Flexibility through joint motions

The Electrodes 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 EL.3.2.2: Decade durability

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

Requirement EL.3.2.3: Functionality after mechanical motions

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

4.0 Technical Requirements Specification

Sections 5 through 7 address technical requirements for the design development and verification of the Electrodes. The technical requirements for the connector and cable of the Electrodes are a subset of those described for the Network Cable in Sections 5 through 7 of *NNP-REQ-0001 – Product Requirements Specification – 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 EL.5.4: Electrical leakage

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

6.0 Connection Requirements

Requirement EL.6.1: Plug-in connector

The Electrodes shall have one two-conductor connector the end of the cable opposite of the tissue-contacting lead.

Requirement EL.6.2: Disconnection without destruction

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

7.0 Reliability Requirements

Requirement EL.7.1: Functionality across stretching

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

Requirement EL.7.2: Functionality across crushing

The Electrodes 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 EL.7.3: Functionality across bending

The Electrodes 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^o.

Requirement EL.7.4: Functionality across twisting

The Electrodes shall remain functional during and after 6 x 10^5 cycles of twisting at a rate of 36º 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

14.2 Related Documents

Document Number	Title
NNP-REQ-0001	Product Requirements Specification – Network Cable

8.3 Definitions

Term	Definition
AIMD	Active Implantable Medical Device
Electrodes	The entire assembly of the connector, cable, and tissue-contacting leads used for stimulation and recording at muscles in the COSMIIC System.

9.0 Revision History

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