

Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix A - Abbreviations

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Appendix A – Abbreviations

Term	Description
AC	Alternating Current
ACK	Acknowledgement Field (software)
AE	Adverse Event
AIMD	Active Implantable Medical Device
AMP	Current Amplitude (stimulus parameter)
AVR-core	A popular microprocessor architecture manufactured by Atmel Corporation.
Battery	A battery consists of two or more cells electrically connected to form a unit
Bipolar electrode	An electrode topology that uses 2 closely spaced contacts for the current return path.
BP2	Two Channel Biopotential Recording Module for the NNP System
BOL	Beginning Of Life (rechargeable cells)
Bootloader	A small program that can re-program and/or load the main application after a processor begins executing code.
C#	#th Cervical Level (e.g., C5 = 5th Cervical Level)
Cable	An assembly of one or more filars in an enveloping jacket. An assembly of one or more insulated conductors.
CAN	Controller Area Network is a message-based communication protocol described by ISO 11898-1.
CANOpen	An open source CAN protocol specification that implements the communication layers above and including the network layer.
Cell	The basic electrochemical element that provides a source of electrical electrical voltage and current
CPLD	Complex Programmable Logic Device
CRC	Cyclic Redundancy Check
C of C	Certificate of Compliance
CT1	Control Tower is the NNP external control unit.
CWRU	Case Western Reserve University
DC	Direct Current
DFT	Drawn Filled Tube. A metal to metal composite wire that is used in the cardiac device industry.
DLC	Data Length Code
DOD	Depth Of Discharge
DSOB	Data Safety Oversight Board
DUT	Device Under Test
DVT	Design Verification Testing is performed to ensure design output meets the design input requirements.
EMG	ElectroMyoGram. Electrical signal from muscles under voluntary control. Interchangeable

	with MES.
EOL	End of life (rechargeable cells)
ESD	Electrostatic Discharge
Failsafe function	A function designed to operate with an exceptionally high confidence level. A failsafe control function is usually independent of other control pathways.
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FES	Functional Electrical Stimulation
FESC	(Cleveland) Functional Electrical Stimulation Center
FESCAN	FES-specific Controller Area Network (network protocol)
Filar	An individual and insulated conductor in a cable
FNS	Functional Neuromuscular Stimulation
Forcing function	An engineering solution that decreases the probability of human error.
FSC	FESCAN Transceiver
FTA	Fault Tree Analysis
GT-NNP System	Grasp and Trunk Networked Neuroprosthetic System
HCN	Host Computer - Notebook
IAP	In-Application Programming
ID	Identification
IEC	International standards
IJAT	Implantable Joint Angle Transducer
INTER	Time Between Stimulus Pulses Across Channels
INTRA	Time Between Stimulus Pulses on a Single Channel
IPI	Interphase Interval (stimulus parameter)
IRS-8	Eight-Channel Implantable Receiver-Telemeter
ISO	International Standards Organization
ISP	In-System Programming
IST-10,-12,-16	Implantable Simulator-Telemeter. A family of Active Implantable Devices Manufactured by the CWRU Cleveland FES Center where the suffix indicates number of channels.
LCD	Liquid Chrystal Display
LT	Lidthrough
MAX	MAXimum
MedRadio	Medical Device Radiocommunications Service (formerly MICS)
MES	Myoelectric Signal. Electrical signal from muscles under voluntary control. Interchangeable with <u>EMG</u> .
МНМС	MetroHealth Medical Center
MICS	Medical Implant Communication Service. Deprecated term for MedRadio.
MIN	MINimum
Monopolar electrode	An electrode topology that uses the device enclosure as the current return path.
MP35N	Metal alloy commonly used in implantable leads.
NC2	Network Cable – Two Conductor

Near field link coil	A coil designed to transcutaneously power the PM1 AIMD via the use of a low frequency alternating magnetic field.
NIH	National Institutes of Health
NMT	Network ManagemenT
NNP	Networked NeuroProsthesis. Interchangeable with NNPS.
NNPS	Networked NeuroProsthesis System. Interchangeable with NNP.
NP	NeuroProsthesis
OD	Object Dictionary. An array of variables with a 16-bit index and an 8-bit subindex. Used to configure the device and return data.
OS	Operating System
OVDA	International association of automation companies
Passive Recovery	A pulse charge recovery method that relies on circuit impedance to limit recovery current.
PCB	Printed Circuit Board
PD	Pulse Duration (stimulus parameter)
PDO	Process Data Object
PEEK	Polyetheretherketone
PFA	PerFluoroAlkoxy is a polymer similar to polytetrafluoroethylene (PTFE) with the alkoxy substituents allowing the polymer to be melt-processed.
PG4	Four Channel Pulse Generator Module for the NNP System.
PM1	Power Module with 1 network bus.
PO	Probability of Occurrence (Risk Analysis)
Pulse	A biphasic waveform consisting of a rectangular, constant current cathodic phase; followed by an interphase delay; followed by a capacitive discharge anodic phase.
RAM	Random Access Memory
REC	Receive Error Counter
RF	Radio Frequency
RM	Remote Module (includes PG4 and BP2)
RPD	Recovery Pulse Duration
RPN	Risk Priority Number (Risk Analysis)
RTOS	Real Time Operating System
S	Severity score (Risk Analysis)
SCI	Spinal Cord Injury
SDO/PDO	Service Data Object/Process Data Object
SOF	Start of Frame
SRR	Substitute Remote Request
SS	Stainless Steel
Start permissive	A condition that must be satisfied for a device to begin operation.
Static magnetic field	A time invariant magnetic field such as that produced by a permanent magnet, or a DC current through a coil, which is stationary relative to the object in question.
Strand	A group of wires helically twisted together
TCP/IP	Common Internet Protocol

TEC	Transmit Error Counter
Tetraplegic	Quadriplegic
TOL	Tolerance
UE	Upper Extremity
UECU	Universal External Control Unit
Unit Testing	Testing performed to ensure a device matches design output specifications.
USB	Universal Serial Bus
VA	(Department of) Veterans Affairs
VAMC	Veterans Affairs Medical Center
Wire	An individual element (typically a cylindrical rod) making up a strand