Section 3 – 510(k) Cover Letter

K141399

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This document contains the information for Stimwave Technologies Incorporated, Freedom Spinal Cord Stimulator (SCS) System submission for market clearance. In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when Stimwave Technologies Incorporated proposes to introduce its Freedom Spinal Cord Stimulator (SCS) System into interstate commerce for commercial distribution. Previous communications related to this submission are found in 510(k) submission K132635 and Q submission Q131489. Stimwave Technologies Incorporated requests to have Kristen Bowsher as our Lead Reviewer as she is familiar with past communication of the product. Previous deficiencies from the K132635/Q131489S001 submission have been addressed and a full response is found in Section 199. The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy. Following contains the regulatory information for the contents of this submission supporting the device's market clearance.

Administrative Information

Submission	May 27, 2014
Registration Number:	Not currently registered
Owner:	Stimwave Technologies Incorporated
Address:	420 Lincoln Road Suite 365 Miami Beach Florida 33139 USA
Phone:	800.965.5134 Ext. 800
Fax:	800.965.5134
Contact:	Elizabeth Greene
Email:	elizabeth@stimwave.com

Device Identification

Type of Submission	Traditional
Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Regulation Classification:	Stimulator, Spinal-Cord, Implanted (Pain Relief)

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Regulation Number:	882.5880
Product Code:	GZB
Device Class:	2
Classification Panel:	Neurology
Model Number(s):	Receiver: FRE4-A001, Receiver Kit: FRE4-A000, Trial: FRT-A001, Trial Kit: FRT4-A000, Wearable Antenna Assembly: WAA-A012, Wearable Antenna Assembly Kit: WAA-A011
Reason for Submission	New device
Prior Related Submissions	K132635, Q131489
Multiple Devices:	None; this is the only device in the submission
FDA Establishment Number:	Not Applicable
Confidentiality Requirements	Please keep all parts of the submission confidential

Design and Use of the Device

Table 3A. Principle Factors

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?	X	

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 800.965.5134 extension 800 or by email at elizabeth@stimwave.com.

Sincerely,

Elizabeth Greene
Regulatory Affairs Manager

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Section 1 - Medical Device User Fee Cover Sheet (FDA Form 3601)

Device Name: Freedom Spinal Cord Stimulator (SCS) System

The FDA Form 3601 Medical Device User Fee Sheet is contained in this section.

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

STIMWAVE TECHNOLOGIES
420 Lincoln Road
Suite 365
Miami Beach
FL 33139
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****7426

2. CONTACT NAME
Laura Perryman
2.1 E-MAIL ADDRESS
laura@stimwave.com
2.2 TELEPHONE NUMBER (include Area code)
480-3717991
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a
[ ] The sole purpose of the application is to support conditions of use for a pediatric

qualified small business, including any affiliates

population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

20-May-2014

"Close Window" Print Cover sheet

Section 2 – CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)

Device Name: Freedom Spinal Cord Stimulator (SCS) System

The CDRH Premarket Review Submission Cover Sheet is contained in this section. Standard Data Report Forms (FDA Forms 3654) for applicable standards are referenced in Section 9 Declaration of Conformity and Summary Reports of this submission.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
05/27/2014	(b)(4) [redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Stimwave Technologies Incorporated	3010676138		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	800-965-5134		
Street Address	FAX Number *(including area code)*		
420 Lincoln Road, Suite 365	800-965-5134		
City	State / Province	ZIP/Postal Code	Country
Miami Beach	FL	33139	United States
Contact Name			
Elizabeth Greene			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	elizabeth@stimwave.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZB	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K934065	1	Mattrix 3271/3272	1	Medtronic
2	K883780	2	Xtrel 3425	2	Medtronic
3	K000852	3	Renew	3	ANS
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1	Freedom Spinal Cord Stimulator System	1	FRE4-A001
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZB	882.5880	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT-A001 device is solely used for trial stimulation of the permanent FRE4-A001 device.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-7	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008/(R)2012	12-10-2008
2	10993-5	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	06-23-2009
3	10993-10	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	09-10-2010
4	10993-11	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 11L Tests for systemic toxicity	2006/(R)2010	10-19-2006
5	10993-3	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	2003/(R)2009	01/01/2009
6	10993-6	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2007/(R)2010	04-11-2007
7	11607-2	AAMI/ANSI/ISO	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2006/(R)2010	12-23-2005

Please include any additional standards to be cited on a separate page.

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SECTION I — UTILIZATION OF STANDARDS

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	Standards No.	Standards Organization	Standards Title	Version	Date
1	11737-1	AAMI/ANSI/ISO	Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed	2008/(R)2012	12-10-2008
2	D4169	ASTM	Standard practice for performance testing of shipping containers and systems (Sterility)	2009	11-01-2009
3	61000-4-2	IEC	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity tests	Ed 2.0 2008	12-01-2008
4	61000-4-8	IEC	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	Ed. 2.0 2009	09-01-2009
5	61000-4-3	IEC	Electromagnetic compatibility (EMC) - Part 4.3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	Ed. 3.2 2010	04-01-2010
6	11	CISPR	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	ED. 5.1B 2010	01-27-2011
7	C95.1	ANSI/IEEE	Standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3kHz to 300GHz	1992	11-18-1992

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SECTION I — UTILIZATION OF STANDARDS

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	Standards No.	Standards Organization	Standards Title	Version	Date
1	1528	IEEE	Recommended practice for determining the peak spatial average specific absorption rate (SAR) in the human head from wireless communication devices: measurement techniques	2003	01-14-2004
2	62209-2	IEC	Human exposure to radio frequency fields from hand-held and body mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedures to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30MH	2010	03-30-3010
3	E3 Test Protocol	GTRI	Test protocol for medical devices to security and logistical system	v5.1 2007	08-01-2007
4	F2182-11a	ASTM	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging	2011a	03-01-2011
5	F2119-07	ASTM	Standard test method for evaluation of MR image artifacts from passive implants (Materials)	2007 Reapproved 2013	09-01-2007
6	F2052-06e1	ASTM	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment (Materials)	2006e1	03-01-2006
7	F2213-05	ASTM	Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment (Materials)	2005 Reapproved 2011	05-01-2006

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SECTION I — UTILIZATION OF STANDARDS

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	Standards No.	Standards Organization	Standards Title	Version	Date
1	10974	ISO/TS	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2012	10-08-2013
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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Section 3 – 510(k) Cover Letter

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This document contains the information for Stimwave Technologies Incorporated, Freedom Spinal Cord Stimulator (SCS) System submission for market clearance. In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when Stimwave Technologies Incorporated proposes to introduce its Freedom Spinal Cord Stimulator (SCS) System into interstate commerce for commercial distribution. Previous communications related to this submission are found in 510(k) submission K132635 and Q submission Q131489. Stimwave Technologies Incorporated requests to have Kristen Bowsher as our Lead Reviewer as she is familiar with past communication of the product. Previous deficiencies from the K132635/Q131489S001 submission have been addressed and a full response is found in Section 199. The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy. Following contains the regulatory information for the contents of this submission supporting the device's market clearance.

Administrative Information

Submission	May 27, 2014
Registration Number:	Not currently registered
Owner:	Stimwave Technologies Incorporated
Address:	420 Lincoln Road Suite 365 Miami Beach Florida 33139 USA
Phone:	800.965.5134 Ext. 800
Fax:	800.965.5134
Contact:	Elizabeth Greene
Email:	elizabeth@stimwave.com

Device Identification

Type of Submission	Traditional
Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Regulation Classification:	Stimulator, Spinal-Cord, Implanted (Pain Relief)

Regulation Number:	882.5880
Product Code:	GZB
Device Class:	2
Classification Panel:	Neurology
Model Number(s):	Receiver: FRE4-A001, Receiver Kit: FRE4-A000, Trial: FRT-A001, Trial Kit: FRT4-A000, Wearable Antenna Assembly: WAA-A012, Wearable Antenna Assembly Kit: WAA-A011
Reason for Submission	New device
Prior Related Submissions	K132635, Q131489
Multiple Devices:	None; this is the only device in the submission
FDA Establishment Number:	Not Applicable
Confidentiality Requirements	Please keep all parts of the submission confidential

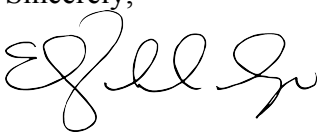
Design and Use of the Device

Table 3A. Principle Factors

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?	X	

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at 800.965.5134 extension 800 or by email at elizabeth@stimwave.com.

Sincerely,



Elizabeth Greene
Regulatory Affairs Manager

Indications for Use Statement

510(k) Number (if known):

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Indications For Use:
The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is solely used for trial stimulation of the permanent FRE4-A001 device.

Prescription Use__X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

for

Freedom Spinal Cord Stimulator (SCS) System

1. Submission Sponsor

Stimwave Technologies Incorporated
420 Lincoln Road
Suite 365
Miami Beach
Florida 33139
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Regulatory Affairs Manager

2. Date Prepared

May 27, 2014

3. Device Identification

Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Classification Regulation:	882.5880
Product Code:	GZB
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

Medtronic Mattrix 3271/3272 Neuromodulation System (K934065)
Medtronic Xtrel, Model Number 3425 Receiver (K883780)
ANS Renew Neurostimulation System Transmitter, Model 2508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343 (K000852)

5. Device Description

The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord SCS System (System) is used for spinal column neural stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an electrical energy field that

acts on nerves near the dorsal column of the spine to inhibit the transmission of pain signals to the brain. The System is comprised of an implantable stimulator (Freedom-4 Stimulator) and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device.

6. Indication for Use Statement

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

7. Substantial Equivalence Discussion

The following table compares the Stimwave Freedom SCS System to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A. Comparison of Characteristics

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Product Code	GZB	GZB and GZF	GZB	GZB
Regulation No.	882.5880	882.5880	882.5880	882.5880
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as Freedom	Same as Freedom	Same as Freedom
Implant Site	Epidural space, L5 to T5	Same as Freedom	Same as Freedom	Same as Freedom
Environmental Use	Hospital, Home	Same as Freedom	Same as Freedom	Same as Freedom
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as Freedom	Same as Freedom	Same as Freedom
Intended User	Layperson	Same as Freedom	Same as Freedom	Same as Freedom
Electrode Material	(b)(4)	Same as Freedom	Same as Freedom	Same as Freedom
Stimulator Body Material		Same as Freedom	Same as Freedom	Same as Freedom
Cable Features		Coiled Wires	Coiled Wires	Braided Wire

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Stimulator Length	(b)(4)	30 to 110 centimeters	30 to 110 centimeters	30 centimeters, and 60 centimeters
Diameter		1.3 millimeters	1.3 millimeters	1.37 millimeters
No. of Electrodes		Same as Freedom	Same as Freedom	4 or 8
Electrode Length		Same as Freedom	Same as Freedom	Same as Freedom
Electrode Spacing		Same as Freedom	Same as Freedom	Same as Freedom
Electrode Surface Area		12.25 mm^2	12.25 mm^2	"Approximately 13 mm^2"
Method of Introduction		Same as Freedom	Same as Freedom	Same as Freedom
Tissue Contact		Same as Freedom	Same as Freedom	Same as Freedom
Sterilization		Same as Freedom	Same as Freedom	Same as Freedom
Labeling		Same as Freedom	Same as Freedom	Same as Freedom
Package		Same as Freedom	Same as Freedom	Same as Freedom
Pulse Frequency		5 to 240 Hertz	5 to 1400 Hertz	Same as Freedom
Pulse Width		50 to 500 microseconds	50 to 1000 microseconds	1 to 500 microseconds
Amplitude (300 Ω)		0 to 7 V	0 to 5.5 V	0 to 20 mA
Amplitude (500 Ω)		0 to 14 V	0 to 10 V	0 to 15 mA
Amplitude (800 Ω)		0 to 12 V	0 to 8.6 V	0 to 12 mA
Waveform		Charge Balanced Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical
Pulse Shape		Decaying Exponential	Decaying Exponential	Decaying Exponential
Average Current Density (300 Ω, 500 Ω)		91.9 mA/cm^2, 146.0 mA/cm^2	70.8 mA/cm^2, 105.0 mA/cm^2	74.4 mA/cm^2, 108.0 mA/cm^2
Charge in 500 µs* (300 Ω, 500 Ω)		11.7 µC/pulse, 14.0 µC/pulse	9.2 µC/pulse, 10.0 µC/pulse	10 µC/pulse, 7.5 µC/pulse
Charge Density in 500 µs* (300 Ω, 500 Ω)		95.2 $\mu C/cm^2$, 114.3 $\mu C/cm^2$	74.8 $\mu C/cm^2$, 81.6 $\mu C/cm^2$	76.9 $\mu C/cm^2$, 57.7 $\mu C/cm^2$
Max Current Density* (300 Ω, 500 Ω)		190.5 mA/cm^2, 228.6 mA/cm^2	149.7 mA/cm^2, 163.3 mA/cm^2	153.9 mA/cm^2, 115.4 mA/cm^2
Average Phase Power (300 Ω, 500 Ω)		0.135 W/phase, 0.172 W/phase	0.080 W/phase, 0.088 W/phase	0.074 W/phase, 0.094 W/phase
Average Phase Power Density (300 Ω, 500 Ω)		0.50 W/cm^2/phase, 1.36 W/cm^2/phase	0.31 W/cm^2/phase, 0.69 W/cm^2/phase	0.29 W/cm^2/phase, 0.74 W/cm^2/phase

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Pulse Delivery Mode	(b)(4)	Continuous	Continuous	Continuous
ON/OFF Times		ON/OFF Cycling Option	ON/OFF Cycling Option	No Cycling
Current Path Options		Bipolar	Bipolar	Bipolar
Power Delivery		Coupled receiver, Radio Frequency transmission	Coupling receiver, Radio Frequency transmission	Coupled receiver, hardwired with connector
Material		Same as Freedom	Same as Freedom	Same as Freedom
Sterile		Same as Freedom	Same as Freedom	Same as Freedom
Single-Use		Yes	Yes	Yes
Shelf Life		1 year	1 year	2 years
Complies with ISO 10993-1		Yes	Yes	Yes
Safety Testing Passed		Yes	Yes	Yes

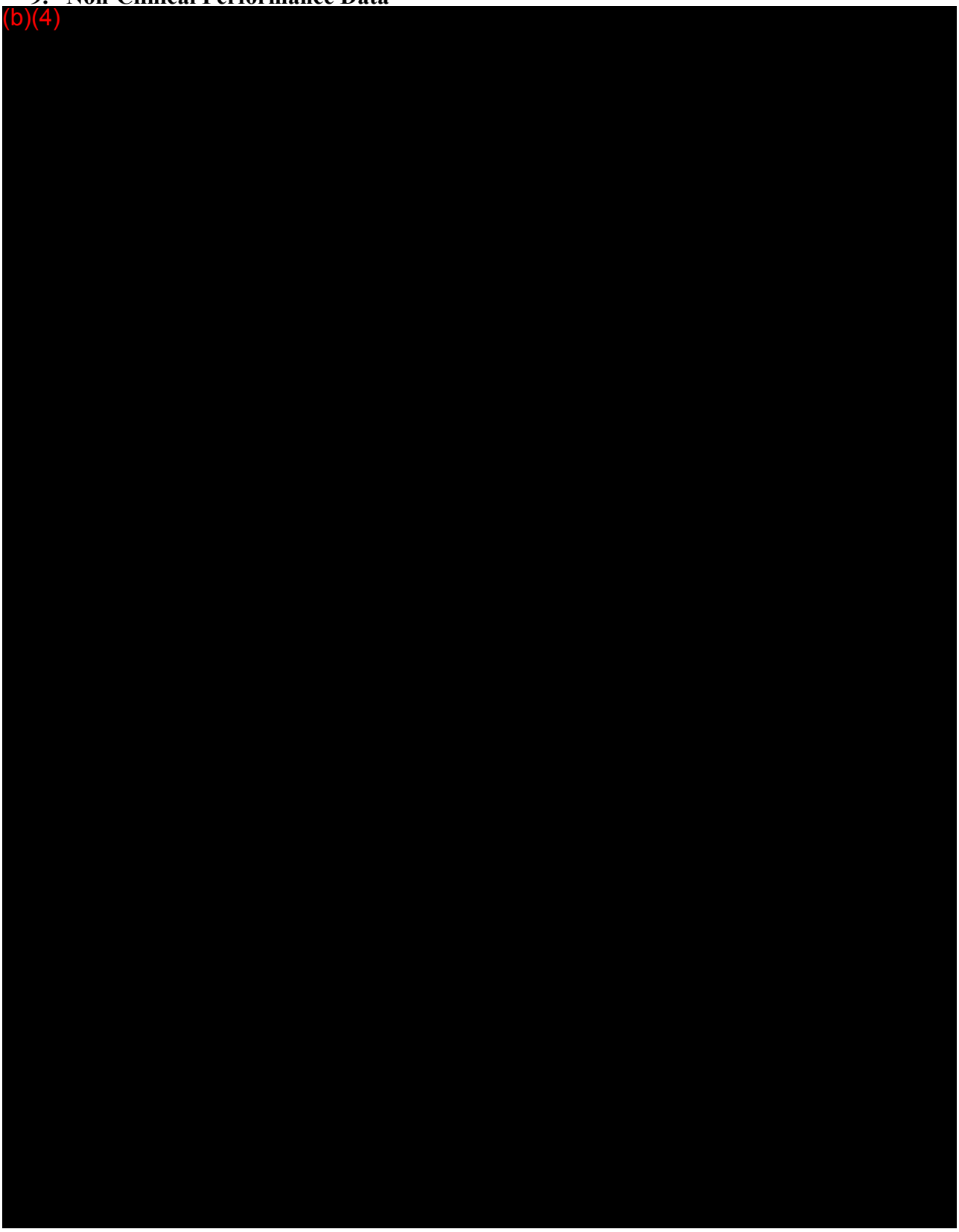
(*) asterisk denotes that formulas were used for the calculations.

8. Biocompatibility Data

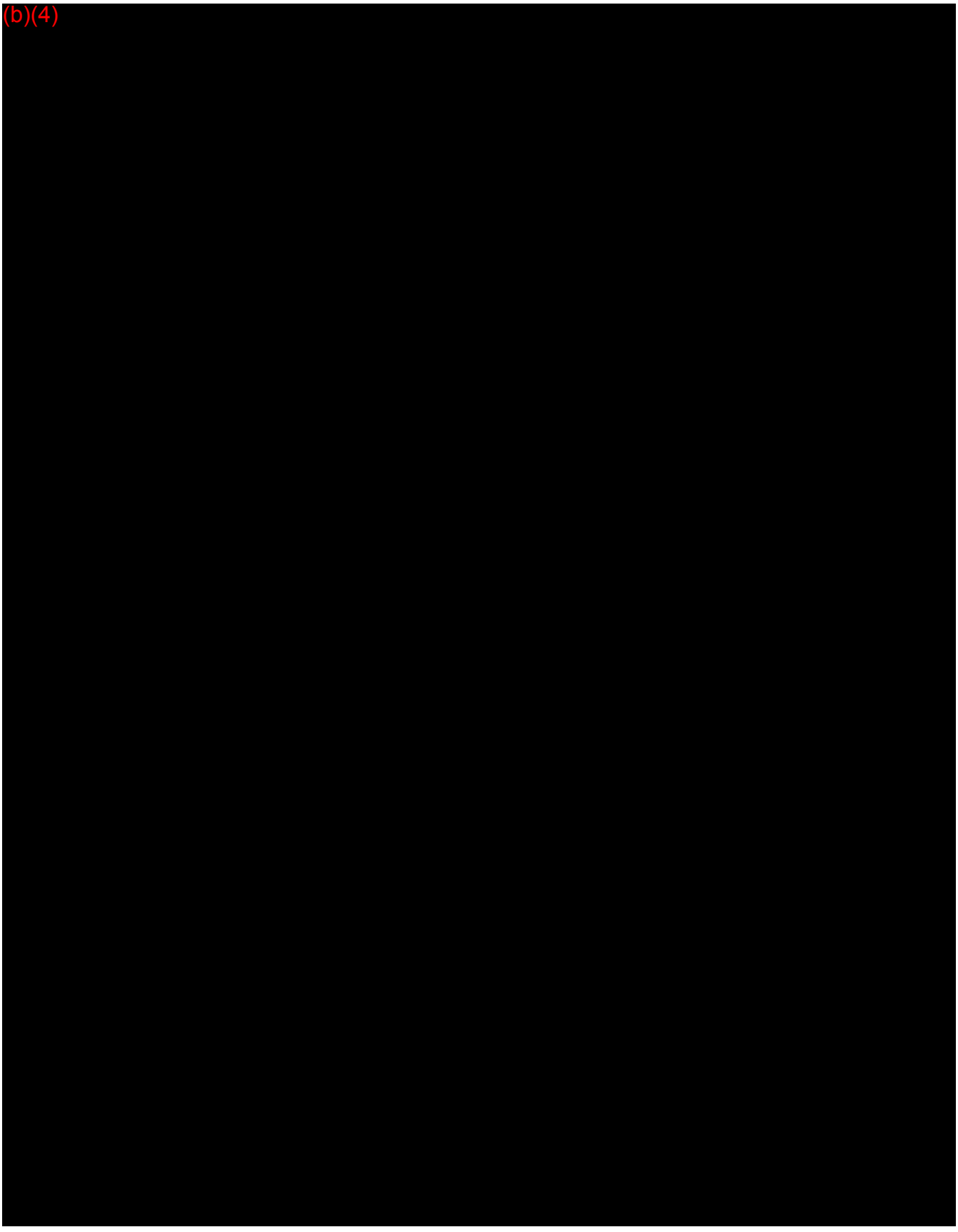
(b)(4)

9. Non-Clinical Performance Data

(b)(4)



(b)(4)



(b)(4)

10. Clinical Performance Data

(b)(4)

11. Statement of Substantial Equivalence

(b)(4)

Section 6 – Truthful and Accurate Statement

(b)(4)

Section 7 – Class III Certification and Summary

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Conclusion:
Not applicable. By the definition of regulation number 882.5880, under product code GZB, an implanted spinal cord stimulators for pain relief is classified as a Class II device.

Section 8 – Financial Certification or Disclosure Statement

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Conclusion:
Not applicable as clinical trials were not performed with the device.

Section 10 - Executive Summary

Device Name: Freedom Spinal Cord Stimulation (SCS) System

Device Name

Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Trade/Proprietary Name:	Freedom Spinal Cord Stimulation (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Model Number(s):	Receiver: FRE4-A001, Receiver Kit: FRE4-A000, Trial: FRT4-A001, Trial Kit: FRT4-A000, Wearable Antenna Assembly: WAA-A012, Wearable Antenna Assembly Kit: WAA-A011
Regulation Number:	882.5880
Classification Panel:	Neurology
Product Code:	GZB
Device Class:	2
FDA Establishment Number:	Not Applicable
Reason:	This is the original submission for this device.

Predicate Devices

510(k) Number:	K934065
Trade Name:	Medtronic Mattrix 3271/3272 Neuromodulation System
Classification Product Code:	GZB and GZF
510(k) Number:	K883780
Trade Name:	Medtronic Xtrel, Model Number 3425 Receiver
Classification Product Code:	GZB
510(k) Number:	K000852
Trade Name:	ANS Renew Neurostimulation System Transmitter, Model 2508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343
Classification Product Code:	GZF and GZB

Device Description

The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord Stimulator (SCS) System (System) is used for spinal cord neural stimulation to provide therapeutic relief for chronic, intractable pain of the back and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an electrical energy field that acts on nerve fibers near or around the dorsal aspect of the spinal column to alter the transmission of pain signals to the brain. The System is comprised of an implantable stimulator (Freedom-4 Stimulator) and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device.

The Freedom-4 Stimulator is a completely sealed device with an embedded receiver placed into the epidural space of the patient parallel to the dorsal spinal column. The receiver is powered from external energy transmitted from the WAA, and generates the stimulation therapy sent to the Freedom-4 Stimulator electrodes.

The Freedom-4 Stimulator and WAA are the two primary products of the Freedom SCS System, as shown in Figure 10A. The Freedom-4 Stimulator is shown in the epidural space of a patient. The WAA is shown worn around the patient's torso. The WAA provides power to the implant and transmits stimulation parameter settings embedded on the carrier 915 MHz frequency, that include the waveform pulse shape, pulse rate, pulse width, and amplitude.

Figure 10A. A sketch of the Freedom SCS System implanted and worn on a patient.

Indications for Use

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulation (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device is for permanent implantation.

The product will be used in the home environment by patients who have chronic low back and/or leg pain. The product should be used during normal everyday activities and is not intended for continuous use during strenuous exercise, swimming, and sleeping.

Materials Statement

(b)(4)

(b)(4)

Table 10A. Patient Contacting Materials

Freedom SCS System	Material(s) Used in Finished Device	Material(s) with Permanent (> 30 days) Contact with Tissue/Bone (according to ISO 10993-1)
Electrodes	(b)(4)	
Multi-Lumen Tubing		
Spacer Tubing		
Flexible Circuit Encapsulation		
Flexible Circuit Substrate		
Flexible Circuit Trace		
Backfill		
Conductor		
Conductor Insulation		
Suture Sleeve Cap		

Contraindications

As documented in the Freedom Spinal Cord Stimulation Instructions for Use (05-0143), patient's contraindicated for the Stimwave Technologies Incorporated Freedom SCS System are those who:

- **Poor surgical risks –** Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general

infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.

- **Pregnancy –** Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Freedom Stimulator or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the stimulator or WAA and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the stimulator and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:
  - Radio or cell phone transmission stations
  - Facilities using radiofrequency heat sealers or induction heaters
  - Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

As documented in the Freedom Spinal Cord Stimulation WAA User Manual (05-0144), patients who are prescribed diathermy must inform the prescribing physician that they CANNOT be exposed to any shortwave, microwave or ultrasound diathermy anywhere on their body because they have an implanted neurostimulation system. Energy from diathermy can be transferred through the implanted system, and can cause tissue damage possibly resulting in injury or death.

Warnings

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.

- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Freedom SCS System is being affected by EMI then you should:

- Immediately move away from the equipment or object.
- Remove the external transmitting device (the Wearable Antenna Assembly (WAA) from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS System. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Stimulator fracture – If the Stimulator insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.
When electrocautery is necessary, these precautions must be followed:

- The WAA should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
  - Only low-voltage modes should be used.
  - The lowest possible power setting should be used.
  - The current path (ground plate) should be kept as far away as possible from the stimulator.
  - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the stimulator is working as intended.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS System with other active implantable or body worn medical devices. These devices include other neurostimulators, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic resonance imaging (MRI) – An MRI examination may be safely performed under certain specific conditions. Refer to the Product Safety Guide for specific MRI guidelines.

The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, and in the process cause serious harm to the patient or other people or damage to the MR system.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator.
The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
  - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
  - Making sure that the X-ray beam does not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the WAA and turn on stimulation.

- Check for proper stimulation, and that indicator lights are operating as expected.
- Shut off the WAA if it is suspected that the device is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a stimulator. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the stimulator. If RF ablation is used, ensure that ablation is not performed over or near the stimulator.

Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with a limited number of security systems, and have demonstrated that the Freedom SCS System (implanted device and WAA) are not affected by close proximity of the security systems. Any security system may temporarily interrupt spinal cord stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels an increase in stimulation near a security system, they promptly move away from the area and remove the WAA from the body.
When possible, it is best to avoid these security systems or to remove the WAA off while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Induced electrical currents can cause heating that may result in tissue damage.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the stimulator site. Magnetic fields will generally not affect the stimulator.

WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

Precautions
As documented in the Freedom Spinal Cord Stimulation Instructions for Use (05-0143), the Freedom SCS System could be impacted by operational changes to the external components through interference by strong electromagnetic interference (EMI) sources (e.g. diathermy, electrocautery, Magnetic Resonance Imaging (MRI), radio-frequency ablation, etc.). Should the system ever stop or change operation as a suspected result of EMI, it should be turned off immediately and the source of EMI should be removed from the proximity.

As documented in the Freedom Spinal Cord Stimulation WAA User Manual (05-0144), patients are advised to ensure the following upon receipt of the WAA:

High-output ultrasonics / lithotripsy – Do not use of high-output ultrasonics or lithotripsy when implanted with a spinal cord stimulator. Use of lithotripsy may result in damage to the device or harm to the patient. If lithotripsy must be used, remove the WAA from the patient and ensure the beam does not focus on the stimulator.

Bone growth stimulators – Do not use a magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient. If a bone growth stimulator must be used, remove the WAA from the patient and ensure that the bone growth stimulator current does not pass over any part of the implanted device.

Dental drills and ultrasonic probes – Do not use dental drills or ultrasonic probes within the vicinity of the Freedom SCS System. Use of dental drills or ultrasonic probes may result in damage to the device or harm to the patient. If a dental drill or ultrasonic probe must be used, remove the WAA from the patient and ensure that the drill/probe does not pass near the stimulator. Keep the drill or probe away from the stimulator.

Electrolysis – Do not use the electrolysis wand within the vicinity of the Freedom SCS System. Use of electrolysis may result in damage to the device or harm to the patient. If electrolysis must be used, remove the WAA from the patient and ensure the wand does not focus near the stimulator.

Laser procedures – Do not use lasers within the vicinity of the Freedom SCS System. Use of lasers may result in damage to the device or harm to the patient. If lasers must be used, remove the WAA from the patient and ensure the laser does not focus near the stimulator.

Radiation therapy – Do not direct high radiation sources such as cobalt 60 or gamma radiation at the device. Use of radiation therapy could cause damage to the device or harm to the patient. If radiation therapy is required near the device, place lead shielding over the device to help prevent radiation damage.

Transcutaneous electrical nerve stimulation – Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the device. Use of TENS could cause the device to turn off or intermittent/increased stimulation. If TENS must be used, remove the WAA from the patient and ensure the TENS is not used anywhere near the stimulator.

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal procedures and should review the procedures described in the Instructions for Use.

Keep the WAA dry – The WAA is not waterproof. Keep it dry to avoid damage. Do not use the WAA when engaging in water activities.

Storage temperatures – The Freedom SCS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact Stimwave if a storage temperature is surpassed.

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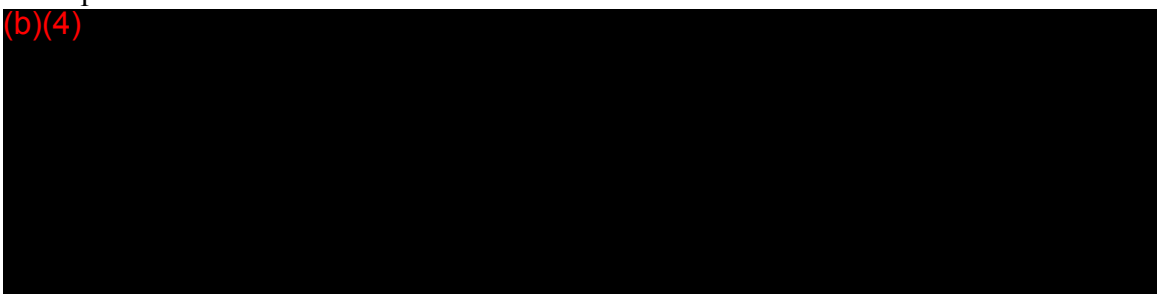

Clean the WAA – Clean the outside of the WAA with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the WAA with care – The WAA is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the WAA out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Airline policies - Follow airline policies for use of medical spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.
Use the WAA as directed – Use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

Do not dismantle the WAA – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

Use of another patient's WAA - Never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your stimulator to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System. However, take care to not put undue stress on the device. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your amplitude to the lowest setting and turn OFF your System before engaging in activities that could become unsafe. Discuss these activities with your clinician.

Comparative Device Summary

The Freedom SCS System shares the same intended use and users as predicate devices. Differences between the predicate devices include the length of the stimulator and stimulation parameters available for the doctor to prescribe. All predicate devices are required to physically connect to another subcutaneous implant, and various lengths are provided for the clinician to select the best length. The Freedom SCS System does not connect to any other component, and thus is offered in only one length currently. Stimulation parameters (pulse frequency, pulse width, and amplitude) are prescribed by the clinician based on feedback from the user's paresthesia coverage. The Freedom SCS System specifications were selected to include the median stimulation parameters.

Predicate devices use a primary cell battery, rechargeable battery, or a RF transmitter that powers and sends parameter settings via coupling to an implanted receiver. The Freedom SCS System also uses a RF signal to transmit power to an implanted receiver. The Freedom SCS System uses a higher carrier frequency then predicate devices that allows for a drastically smaller implanted receiver. Advances in miniaturization of electronics allow for the inclusion of the receiver into the Freedom-4 Stimulator body. A comparison of predicate devices is provided in Table 10B.

Table 10B. Comparison of the Stimwave Freedom SCS System to predicate devices

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Product Code	GZB	GZB and GZF	GZB	GZB
Regulation No.	882.5880	882.5880	882.5880	882.5880
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as Freedom	Same as Freedom	Same as Freedom
Implant Site	Epidural space, L5 to T5	Same as Freedom	Same as Freedom	Same as Freedom
Environmental Use	Hospital, Home	Same as Freedom	Same as Freedom	Same as Freedom
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as Freedom	Same as Freedom	Same as Freedom
Intended User	Layperson	Same as Freedom	Same as Freedom	Same as Freedom
Electrode Material	(b)(4)	Same as Freedom	Same as Freedom	Same as Freedom
Stimulator Body Material		Same as Freedom	Same as Freedom	Same as Freedom
Cable Features		Coiled Wires	Coiled Wires	Braided Wire
Stimulator Length		30 to 110 centimeters	30 to 110 centimeters	30 centimeters, and 60 centimeters
Diameter		1.3 millimeters	1.3 millimeters	1.37 millimeters
No. of Electrodes		Same as Freedom	Same as Freedom	4 or 8
Electrode Length		Same as Freedom	Same as Freedom	Same as Freedom
Electrode Spacing		Same as Freedom	Same as Freedom	Same as Freedom
Electrode Surface Area		12.25 mm^2	12.25 mm^2	"Approximately 13 mm^2"
Method of Introduction		Same as Freedom	Same as Freedom	Same as Freedom
Tissue Contact		Same as Freedom	Same as Freedom	Same as Freedom
Sterilization		Same as Freedom	Same as Freedom	Same as Freedom

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
	(b)(4)			
Labeling		Same as Freedom	Same as Freedom	Same as Freedom
Package		Same as Freedom	Same as Freedom	Same as Freedom
Pulse Frequency		5 to 240 Hertz	5 to 1400 Hertz	Same as Freedom
Pulse Width		50 to 500 microseconds	50 to 1000 microseconds	1 to 500 microseconds
Amplitude (300 Ω)		0 to 7 V	0 to 5.5 V	0 to 20 mA
Amplitude (500 Ω)		0 to 14 V	0 to 10 V	0 to 15 mA
Amplitude (800 Ω)		0 to 12 V	0 to 8.6 V	0 to 12 mA
Waveform		Charge Balanced Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical
Pulse Shape		Decaying Exponential	Decaying Exponential	Decaying Exponential
Average Current Density (300 Ω, 500 Ω)		91.9 mA/cm^2, 146.0 mA/cm^2	70.8 mA/cm^2, 105.0 mA/cm^2	74.4 mA/cm^2, 108.0 mA/cm^2
Charge in 500 µs* (300 Ω, 500 Ω)		11.7 µC/pulse, 14.0 µC/pulse	9.2 µC/pulse, 10.0 µC/pulse	10 µC/pulse, 7.5 µC/pulse
Charge Density in 500 µs* (300 Ω, 500 Ω)		95.2 µC/cm^2, 114.3 µC/cm^2	74.8 µC/cm^2, 81.6 µC/cm^2	76.9 µC/cm^2, 57.7 µC/cm^2
Max Current Density* (300 Ω, 500 Ω)		190.5 mA/cm^2, 228.6 mA/cm^2	149.7 mA/cm^2, 163.3 mA/cm^2	153.9 mA/cm^2, 115.4 mA/cm^2
Average Phase Power (300 Ω, 500 Ω)		0.135 W/phase, 0.172 W/phase	0.080 W/phase, 0.088 W/phase	0.074 W/phase, 0.094 W/phase
Average Phase Power Density (300 Ω, 500 Ω)		0.50 W/cm^2/phase, 1.36 W/cm^2/phase	0.31 W/cm^2/phase, 0.69 W/cm^2/phase	0.29 W/cm^2/phase, 0.74 W/cm^2/phase
Pulse Delivery Mode		Continuous	Continuous	Continuous
ON/OFF Times		ON/OFF Cycling Option	ON/OFF Cycling Option	No Cycling
Current Path Options		Bipolar	Bipolar	Bipolar
Power Delivery		Coupled receiver, Radio Frequency transmission	Coupling receiver, Radio Frequency transmission	Coupled receiver, hardwired with connector
Material		Same as Freedom	Same as Freedom	Same as Freedom

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
	(b)(4) (b)			
Sterile	(b)(4) (b)	Same as Freedom	Same as Freedom	Same as Freedom
Single-Use	(b) s	Yes	Yes	Yes
Shelf Life	(b)	1 year	1 year	2 years
Complies with ISO 10993-1	(b)	Yes	Yes	Yes
Safety Testing Passed	(b)	Yes	Yes	Yes

(*) asterisk denotes that formulas were used for the calculations.

Technology
Receiver Kit

(b)(4)

(b)(4)

WAA Kit

(b)(4)

Performance Summary

(b)(4)

Mechanical Testing

(b)(4)

(b)(4)

Environmental Testing

(b)(4)

Electrical Testing

(b)(4)

EMI/EMC Testing

(b)(4)

(b)(4)

SAR Testing

(b)(4)

Biocompatibility

(b)(4)

(b)(4)

Software Verification and Validation

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(b)(4)

Package Testing

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Conclusion

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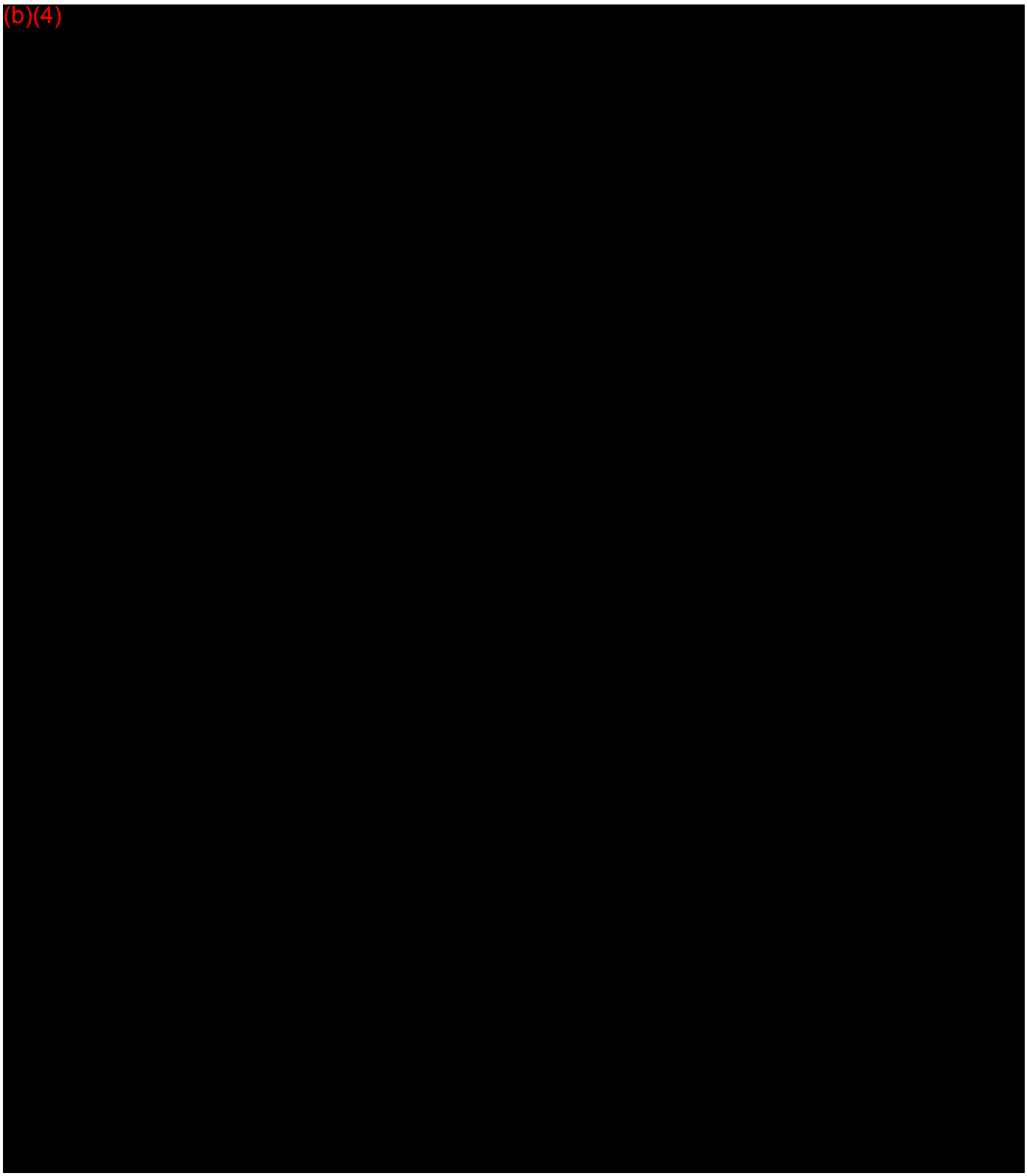
(b)(4)



Section 14 – Sterilization and Shelf Life

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Discussion Summary

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Validation Method of Sterilization Process

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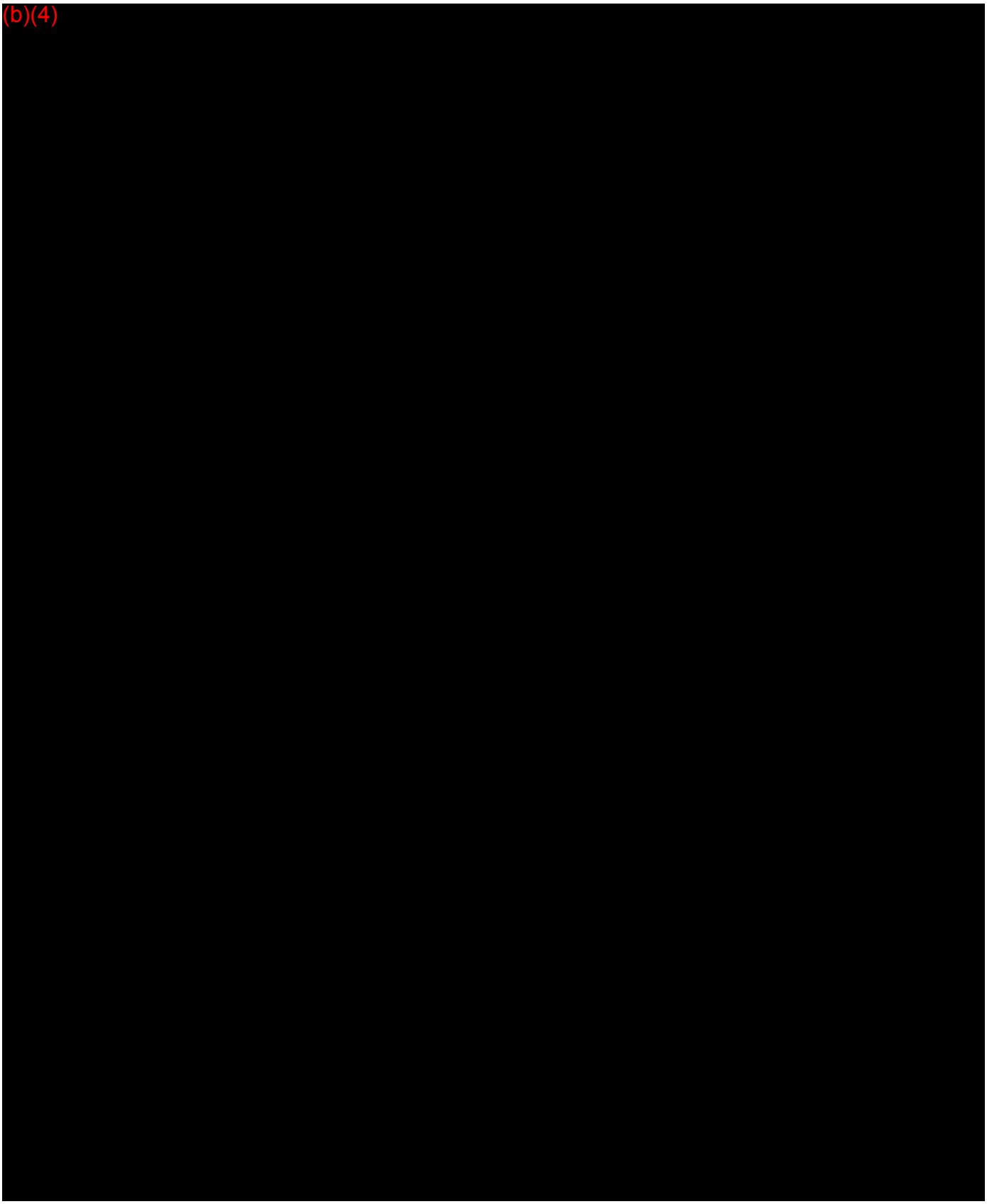

Pyrogenicity Testing

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Bioburden Testing

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Shelf Life

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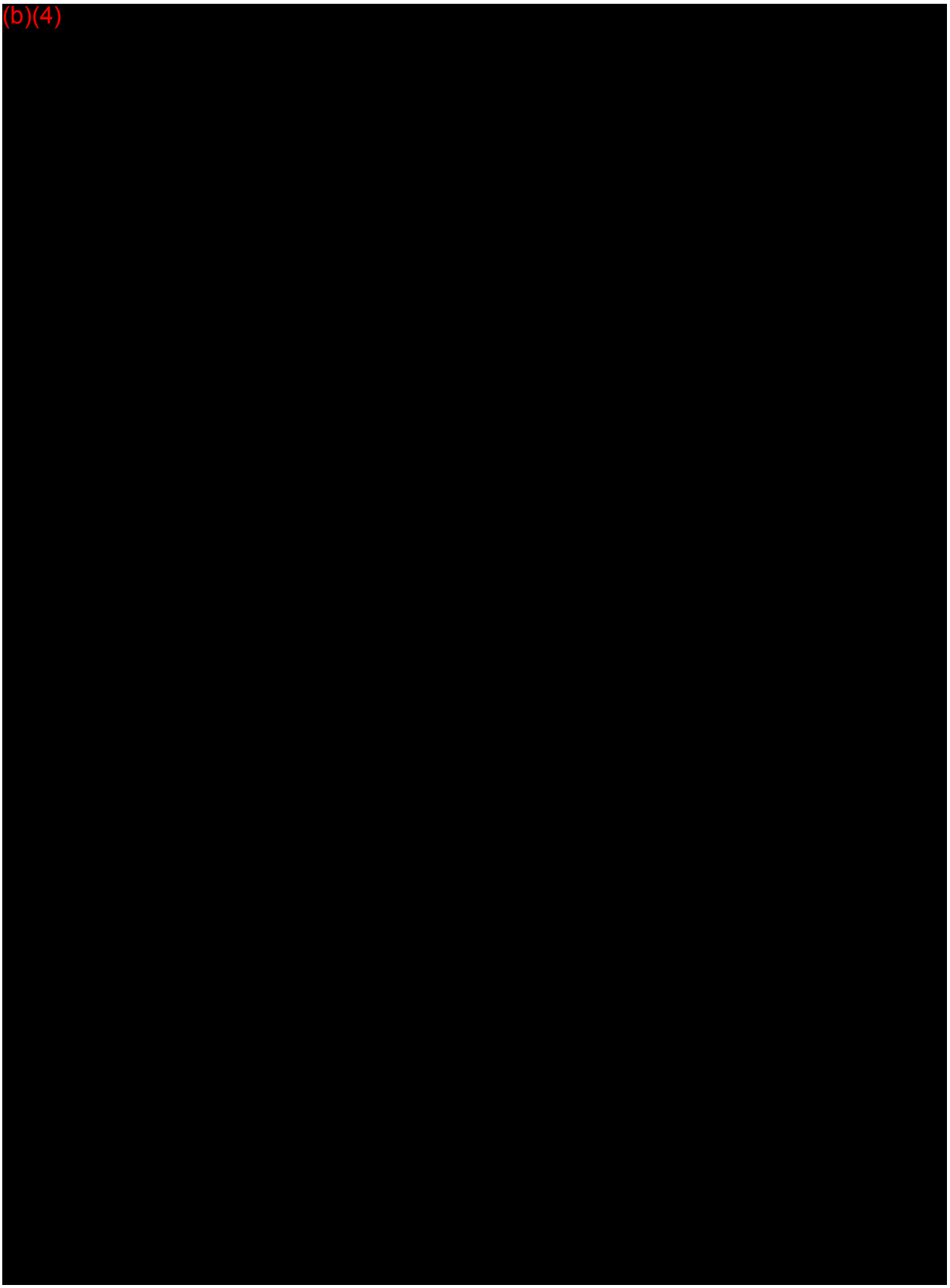

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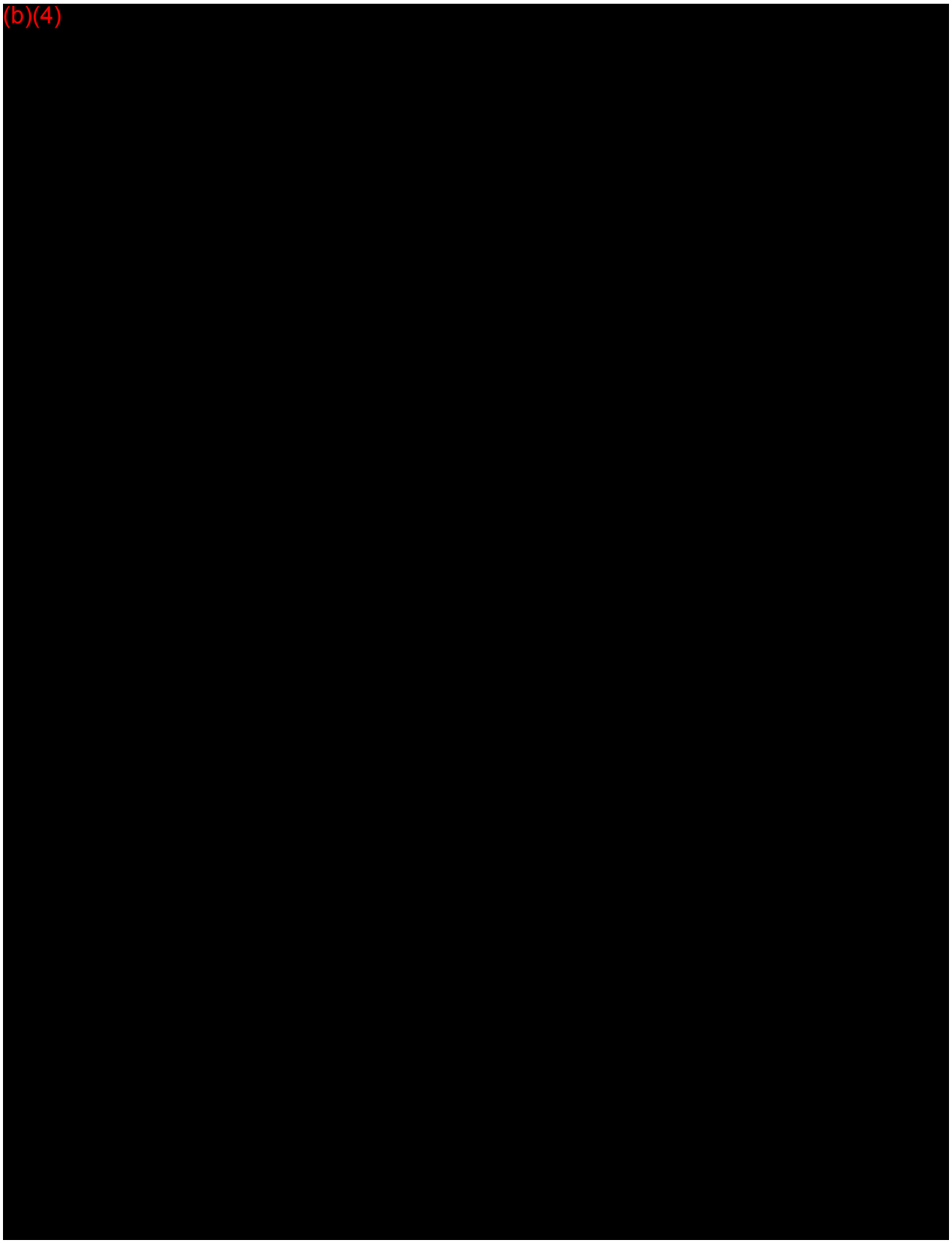

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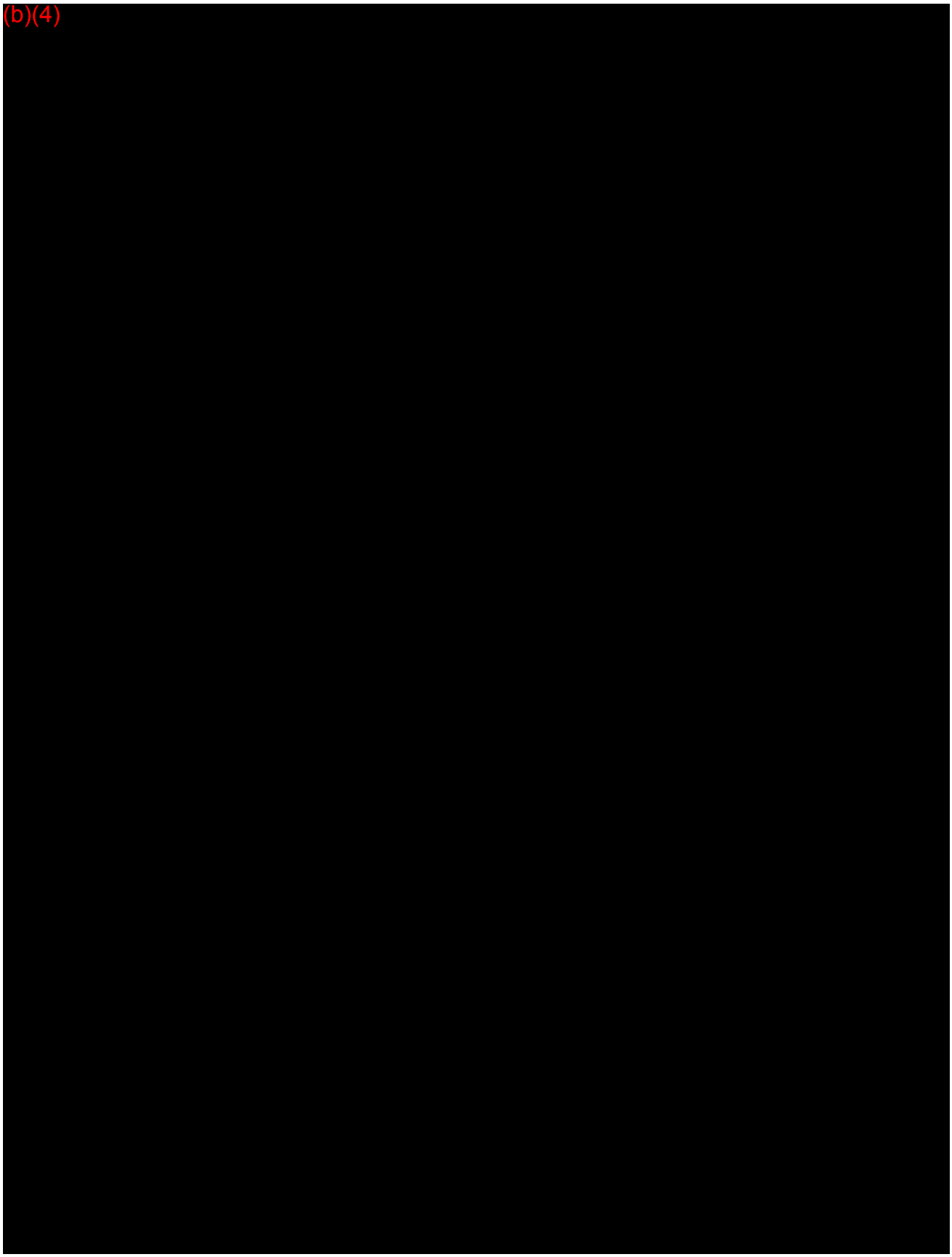

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Sterilization and Shelf Life Summary

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Packaging and Stability Summary

(b)(4)

(b)(4)

Test Reports **Exhibits**

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Receiver Kit

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Wearable Antenna Assembly (WAA) Kit

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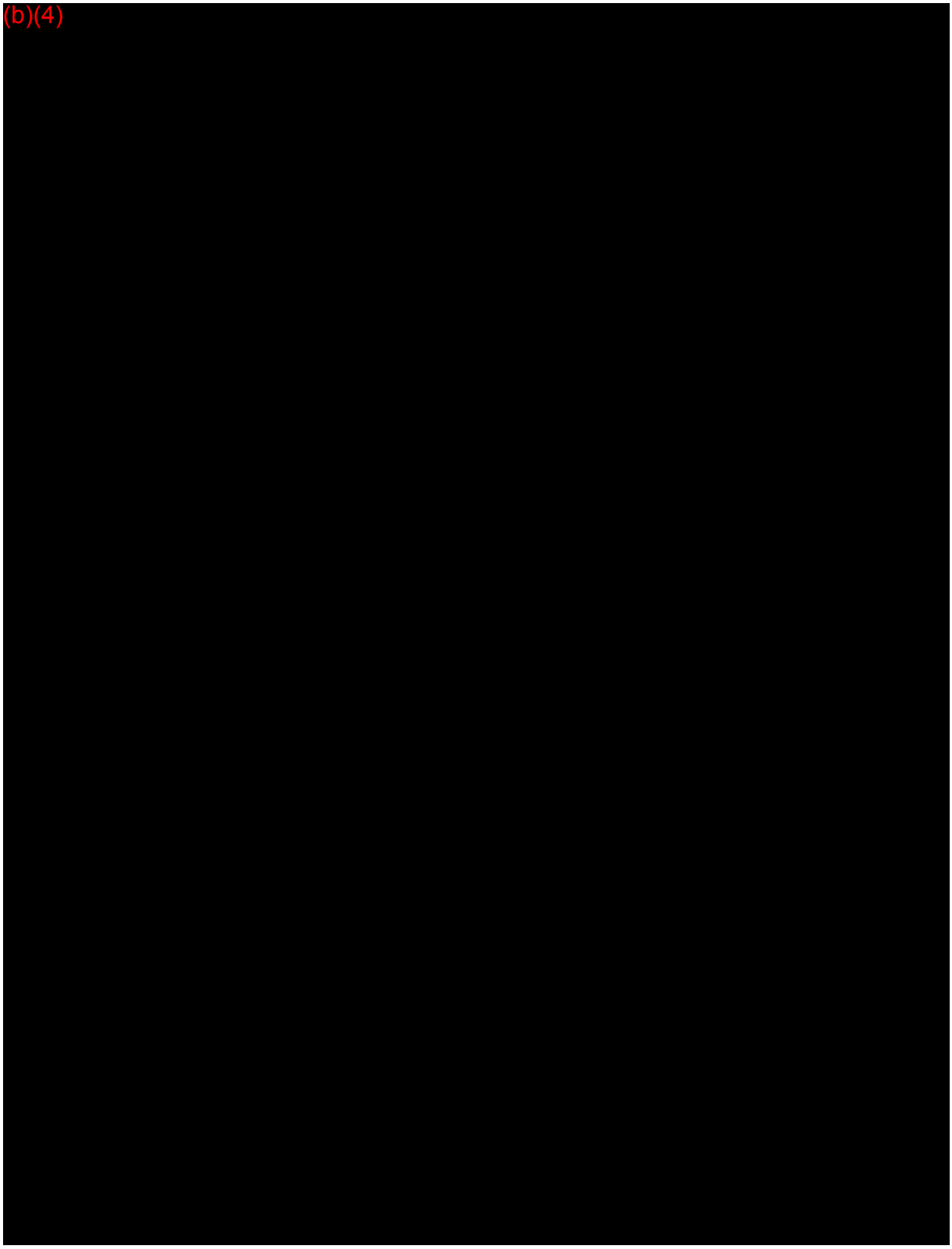

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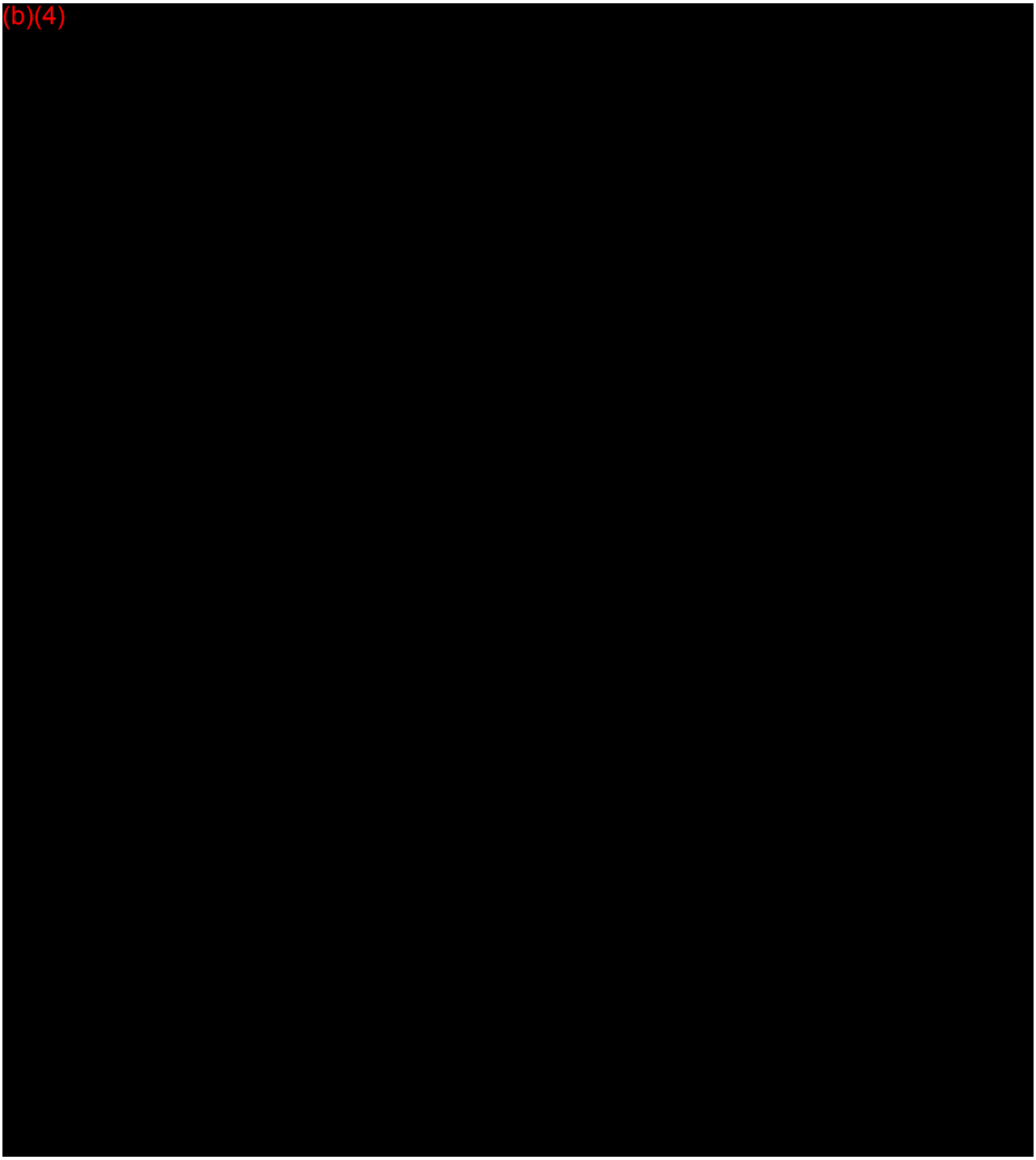

Section 15 – Biocompatibility

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Implant Categorization

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Evaluation Tests

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Biocompatibility Testing

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Samples for Biocompatibility

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(b)(4)

Cytotoxicity

(b)(4)

Sensitization

(b)(4)

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Irritation and Intracutaneous Reactivity

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Acute Systemic Toxicity

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Genotoxicity

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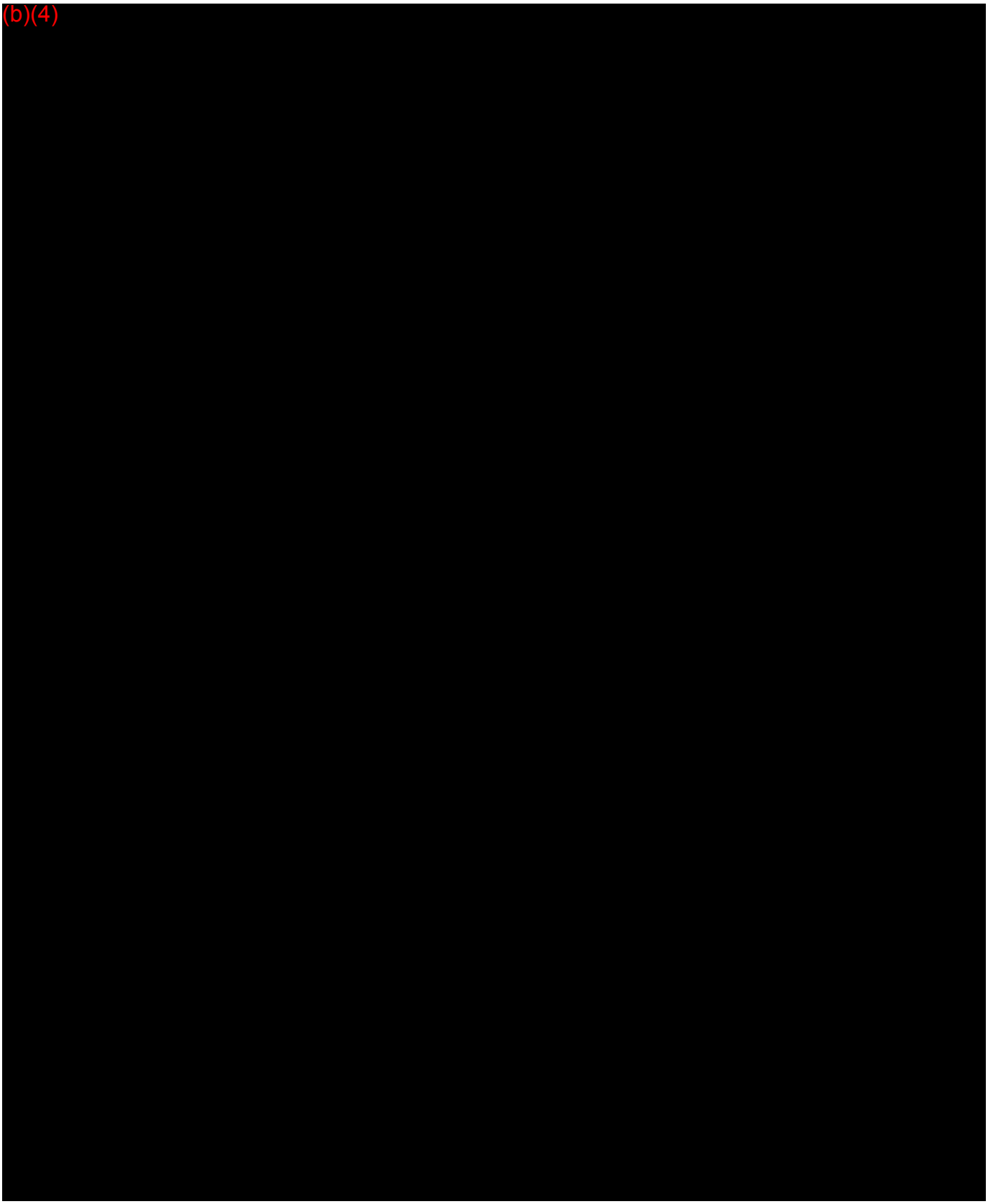

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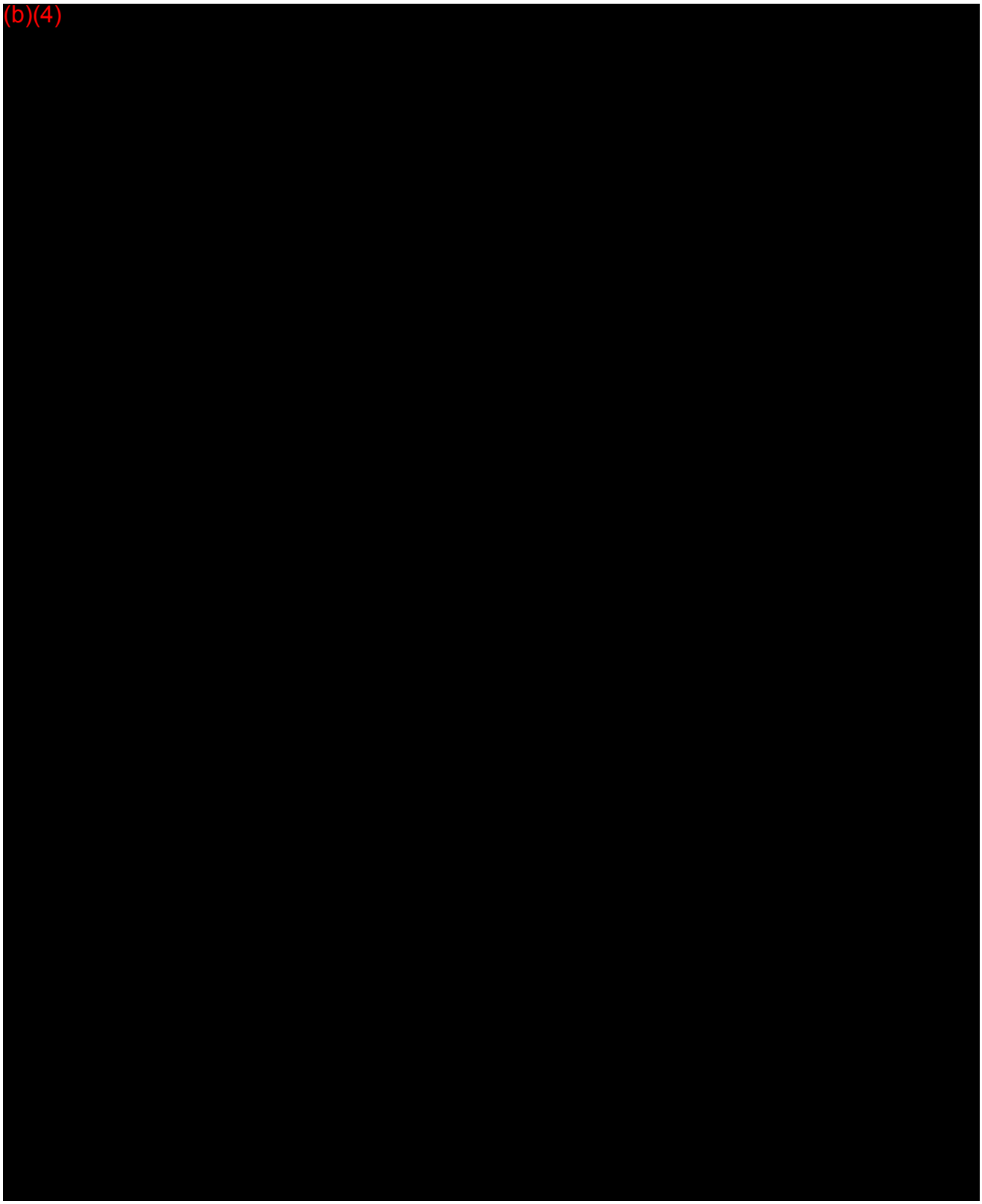

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Implantation

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Subchronic Toxicity

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Chronic, and Carcinogenicity

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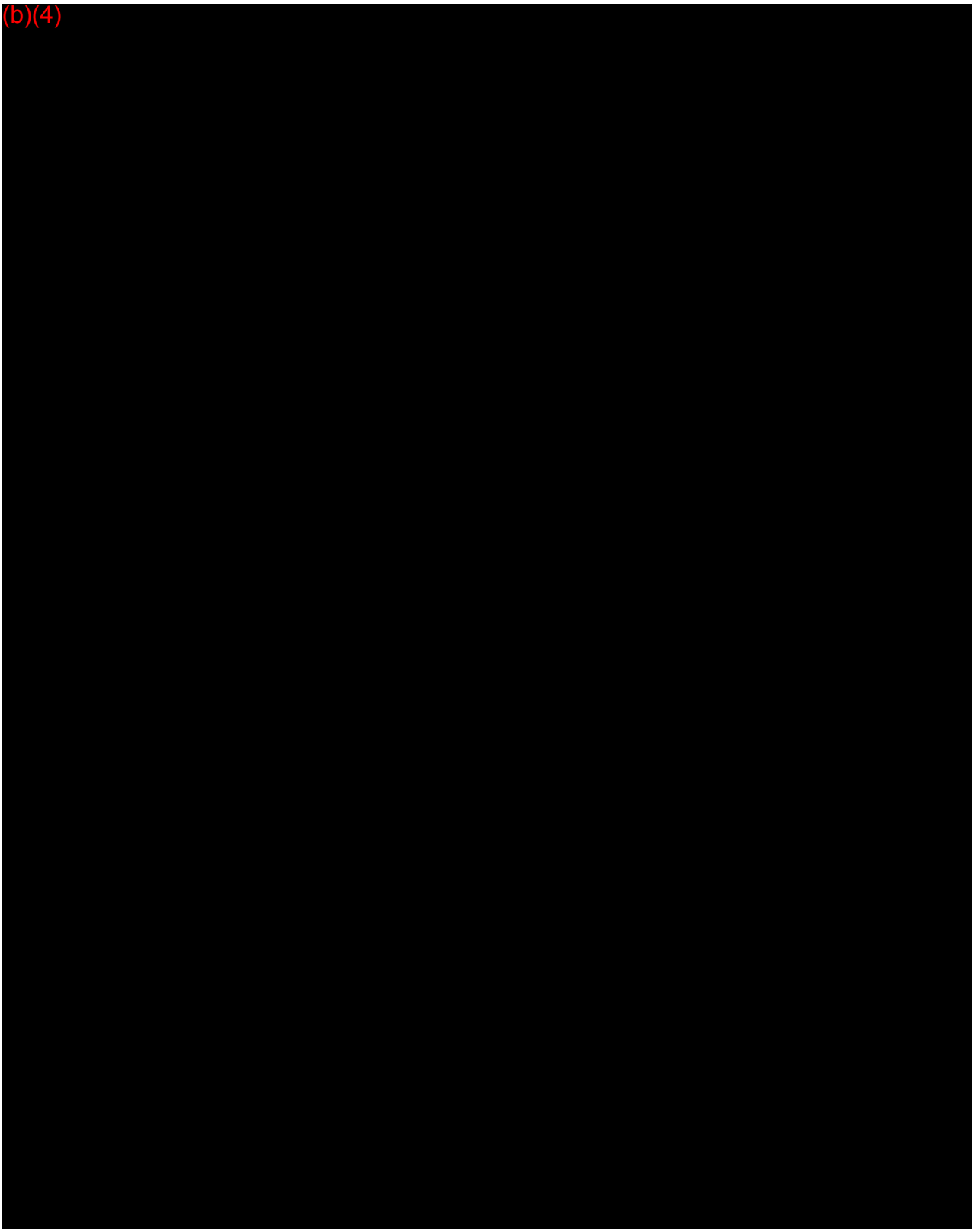

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Manufacturing, Packaging, and Sterilization Considerations

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Biocompatibility of the WAA

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Conclusion

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Section 16 - Software and Firmware

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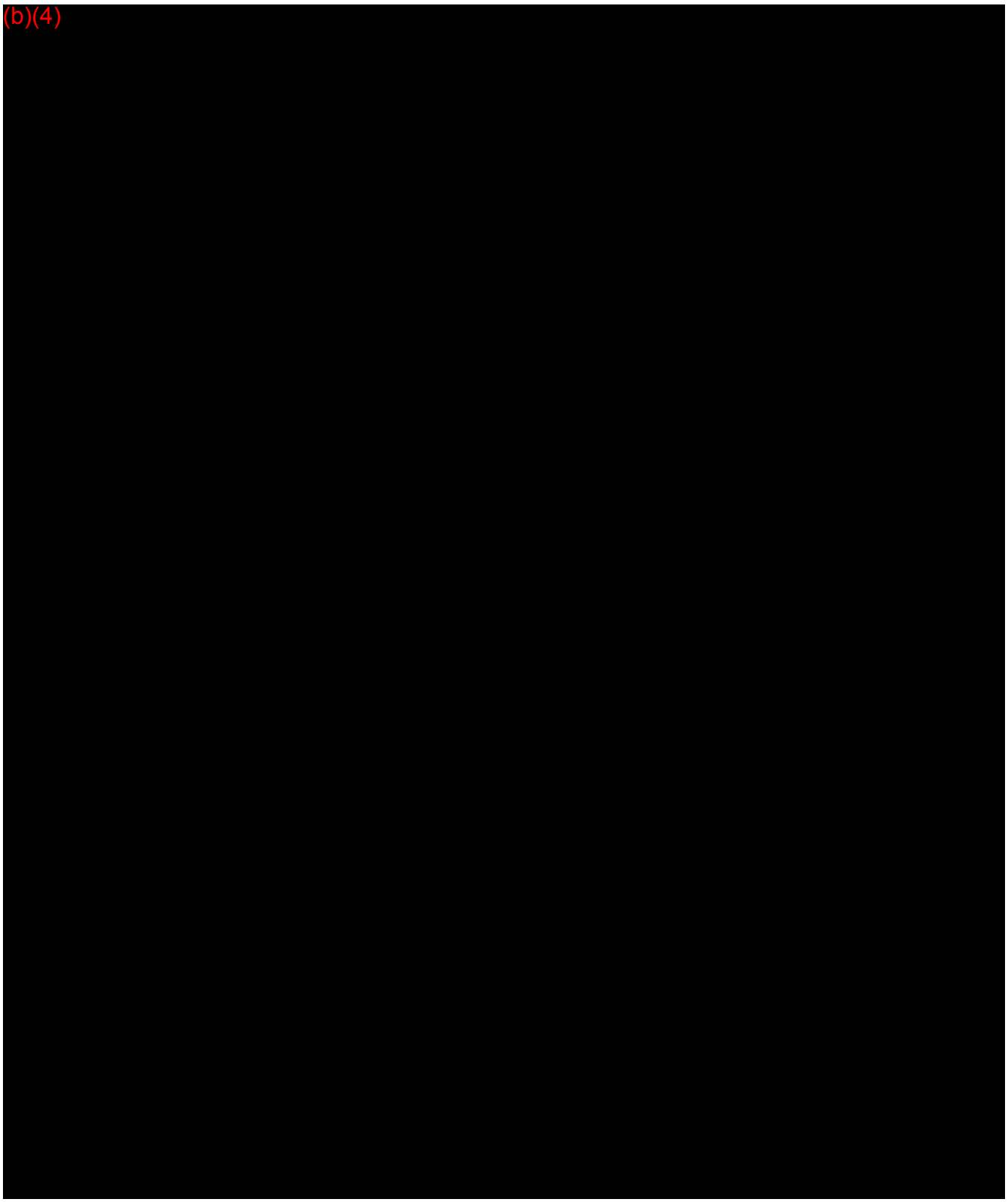

(b)(4) Device Software Data

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-7:2008(R)2012 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-278		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Blue Book Memorandum #G95-1

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-11:2006/(R)2010 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxcity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-11:2006/(R)2010 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxcity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-3:2003/(R)2009 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity,

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993"

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-3:2003/(R)2009 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity,

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-6:2007/(R)2010 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-278	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-6:2007/(R)2010 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11607-1:2006/(R) 2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 11607-1:2006/(R) 2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11607-2:2006/(R)2010 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for f

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-194	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 11607-2:2006/(R)2010 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for f

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED *

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI ISO 11135-1:2007 Sterilization of heath care products - Ethylene oxide – Part 1: Requirements for the development, v

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11737-1:2006 (R)2011 Sterilization of medical devices – Microbiological methods Part 1: Determination of the p

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 11737-1:2006 (R)2011 Sterilization of medical devices – Microbiological methods Part 1: Determination of the p

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D4169-09, Standard practice for performance testing of shipping containers and systems. (sterility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-300	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM D4169-09, Standard practice for performance testing of shipping containers and systems. (sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 14708-3:2008-01-01 Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostim

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 17-10	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 14708-3:2008-01-01 Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostim

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 14971:2007/(R) 2010 Medical devices - Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-70	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 14971:2007/(R) 2010 Medical devices - Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 15223-1 Second Edition 2012-07-01 Medical devices - Symbols to be used with medical device labels, labeling and informatio

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 15223-1 Second Edition 2012-07-01 Medical devices - Symbols to be used with medical device labels, labeling and informatio

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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STANDARD TITLE [1]

AAMI ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R)2012 Medical electrical equipment - Part 1-2: General requirements for b

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R)2012 Medical electrical equipment - Part 1-2: General requirements for

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.9.3	Spaces filled by insulating compound	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have insulating compound

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.11	Mains Parts, components and layout	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not connect to Mains

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.2	Hazards associated with moving parts	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have moving parts

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.4	Instability hazards	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have instability hazards

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.5	Expelled parts hazards	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have expelled parts

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.6	Acoustic energy and vibration	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have acoustic energy or vibrations

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.7	Pressure vessels and parts subject to peumatic and hydraulic pressure	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have pressure

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.8	Hazards associated with support systems	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not have support system

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.1-10.2	X-Radiation and Alpha, beta, gamma, neutron and other particle radiation	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not produce these types of radiation

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.4-10.7	Lasers, visible electromagnetic radiation, infrared, and ultraviolet	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment does not produce these types of radiation

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11.3-11.5	Fire enclosures of ME Equipment, use with flammable anesthetics, and use wit	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment not intended to be used with flammable materials

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11.7	Biocompatibility of ME Equipment	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment not intended to directly contact human tissue

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11.8	Interruption of the power supply to ME Equipment	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment not connected to mains

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15.2	Serviceability	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment not intended to be serviced

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15.4.3.4	Lithium batteries	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

ME Equipment's lithium battery is not tested to IEC 60086-4 or 62133. The battery is instead certified UL1642

DESCRIPTION

JUSTIFICATION

The battery is a single cell secondary battery with regulator and Qi charging compliant. UL1642 certification mitigates the risks.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15.5	Mains Supply Transformers	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment not connected to mains

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16.4-16.5	Enclosures, Separation Devices	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

No contact can be made with electronics, ME Equipment does not have maintenance, calibration or removal of currents.

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16.9	ME System connections and wiring	☑ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment wiring and connections not accessible by user or technician. Incorrect connections cannot be made.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-54		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.1.3	Protection of other equipment from low-frequency magnetic fields	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment is not connected to Mains line

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.5	Surges	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment is internally powered, not connected to Mains line

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STANDARD TITLE

AAMI ANSI IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.7	Voltage dips, short interruptions, and voltage variations on power sully input li	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

ME Equipment is not connected to Mains line

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-11 Edition 1.0:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential perf

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-58	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
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Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-11 Edition 1.0:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential perf

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharg

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharg

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

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JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency mag

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 61000-4-2:2009 Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency mag

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 61000-4-3:2010 Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequ

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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STANDARD TITLE

IEC 61000-4-3:2010 Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequ

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CISPR 11 ED. 5.1 B:2010 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
CISPR 11 ED. 5.1 B:2010 Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/IEEE C95.1-1992 Standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3kHz t

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/IEEE C95.1-1992 Standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3kHz t

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEEE 1528-2003 Recommended practice for determining the peak spatial average specific absorption rate (SAR) in the human head

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEEE 1528-2003 Recommended practice for determining the peak spatial average specific absorption rate (SAR) in the human head

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62209-2:2010 Human exposure to radio frequency fields from hand-held and body mounted wireless communication devices –

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 62209-2:2010 Human exposure to radio frequency fields from hand-held and body mounted wireless communication devices –

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

GTRI E3 Test Protocol v5.1 2007 Test protocol for medical devices to security and logistical systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

GTRI E3 Test Protocol v5.1 2007 Test protocol for medical devices to security and logistical systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI IEC 62304:2006 Medical device software - Software life-cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 13-32	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☑
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI IEC 62304:2006 Medical device software - Software life-cycle processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI IEC 62366:2007 Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-67	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usa

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI IEC 62366:2007 Medical devices - Application of usability engineering to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

BS EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part1: Requi

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3]	# Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

BS EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part1: Requi

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 1041:2008 Information supplied by the manufacturer of medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3]	# Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 1041:2008 Information supplied by the manufacturer of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2182-11a Standard test method for measurement of radio frequency induced heating on or near passive implants during m

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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PSC Graphics (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2182-11a Standard test method for measurement of radio frequency induced heating on or near passive implants during m

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2119-07 (Reapproved 2013) Standard test method for evaluation of MR image artifacts from passive implants. (Materials)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 8-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2119-07 (Reapproved 2013) Standard test method for evaluation of MR image artifacts from passive implants. (Materials)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2052-06e1 Standard test method for measurement of magnetically induced displacement force on medical devices in the m

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 8-124	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2052-06e1 Standard test method for measurement of magnetically induced displacement force on medical devices in the m

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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JUSTIFICATION

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Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2213-05 (Reapproved 2011) Standard test method for measurement of magnetically induced torque on medical devices in t

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 8-128	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2213-05 (Reapproved 2011) Standard test method for measurement of magnetically induced torque on medical devices in

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60529:2001 Edition 2.1 Degrees of protection provided by enclosures (IP Code)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: _____

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PSC Graphics (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60529:2001 Edition 2.1 Degrees of protection provided by enclosures (IP Code)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO/TS 10974:2012 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# Not Applicable	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO/TS 10974:2012 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL	ALL	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
A		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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CONTACT INFORMATION

- MANUFACTURER

(b)(4)

Freedom Spinal Cord Stimulator (SCS) System

WAA Specifications

Prepared by: (b)(4)

Approved by:

(b)(4)

Table of Contents

3.4 Quality

Quality is responsible for controlling documentation of design inputs, external documentation and product specifications.

4.0 System Overview

(b)(4)

Freedom Spinal Cord Stimulator (SCS) System

Battery Charger Specifications

Prepared by: (b)(4)

Approved by: (b)(4)

(b)(4)

Table of Contents

(b)(4)

3.3 Management

Management is responsible for review and approval of the product specifications and their ability to meet the product requirements. When necessary, *Management* will work with *Engineering* and *Manufacturing* for determination of product specifications.

3.4 Quality

Quality is responsible for controlling documentation of design inputs, external documentation and final product specifications. *Quality* will ensure that the risks associated with the product specifications are analyzed and mitigated before implemented into Pilot Production.

4.0 Specifications Trace

The product specifications for the Battery Charger based on the Battery Charger Requirements are presented in Section 4.1. This trace matrix details the design specification, and identifies the applicable section of this document for the Specification.

4.1 Requirements Trace Matrix

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[redacted]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Mr. Rashmi Moza
Regulatory Affairs Specialist
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100
Plano, Texas 75024

Re: K000852
Trade Name: ANS Renew Neurostimulation System Transmitter, Model 3508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343
Regulatory Class: II
Product Code: GZF and GZB
Dated: October 20, 2000
Received: October 23, 2000

Dear Mr. Michael:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
0900262181a3e7e6.pdf
System attempted to attach the file. Please look at attachments to open this file manually.

Stimwave Technologies, Inc.

Lead Kit + Introducer Kit

Accelerated Aging & Package Testing

(b)(4)

(b)(4) **Final Report**

(b)(4)

(b

Life Science Outsourcing, Inc.

Stimwave Technologies, Inc.

Lead Kit + Introducer Kit

DISTRIBUTION SIMULATION

(b)(4)

(b)(4)

PROTOCOL

(b)(4)

Life Science Outsourcing, Inc.

Stimwave Technologies, Inc.

ASTM D4169-09
Distribution Simulation

Test Plan:	(b)(4)
Date(s) Tested:	
Sample(s) Tested:	
Product Name:	
Work Order:	
Protocol / Study:	
Lab Technician:	
Reviewed By:	

(b)(4)

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FINAL GLP REPORT: (b)(4)

SUBCUTANEOUS IMPLANTATION – ISO
(b)(4)

Test Article
(b)(4)

21 CFR Part 58 Compliance
GLP for Nonclinical Laboratory Studies

(b)(4)

Sponsor
Stimwave Technologies Incorporated
9375 East Shea Boulevard
Suite 147
Scottsdale, AZ 86520

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(b)(4) [redacted]

Summary of Biocompatibility Evaluation

Confidential

(b)(4)

Cytotoxicity - ISO MEM Elution using L-929 Mouse Fibroblast Cells

(b)(4)

Freedom Spinal Cord Stimulator (SCS) System

915 Software Requirements Specification

Table of Contents

(b)(4)

Stimwave Technologies, Inc.

WAA 915 MHz Device

FCC 18.305:2013

Report (b)(4)

Report Prepared By (b)(4)

(b)(4)

(b)(4)

STIMWAVE TECHNOLOGIES FREEDOM SCS SYSTEM E3 TESTS TO REPRESENTATIVE SECURITY AND LOGISTICAL SYSTEMS IN THE GTRI MEDICAL DEVICE TEST CENTER

(b)(4)

(b)(4)

Submitted to

Stimwave Technologies, Inc.
9375 E Shea Blvd, Suite 147
Scottsdale, AZ 85260

(b)(4)

(b)(4)

(b)(4)

(b)(4)

STIMWAVE TECHNOLOGIES FREEDOM SCS SYSTEM E3 TESTS TO REPRESENTATIVE SECURITY AND LOGISTICAL SYSTEMS IN THE GTRI MEDICAL DEVICE TEST CENTER

(b)(4)

Submitted to

Stimwave Technologies, Inc.
9375 E Shea Blvd, Suite 147
Scottsdale, AZ 85260

(b)(4)

ATTACHMENT 1

E3 TEST PROTOCOL FOR MEDICAL DEVICES TO SECURITY AND LOGISTICAL SYSTEMS

(b)(4)

E3 TEST PROTOCOL
FOR
MEDICAL DEVICES
TO
SECURITY AND LOGISTICAL SYSTEMS

(b)(4)

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(b)(4)

(b)(4)

TEST REPORT (b)(4)
of Medical Device – Belt/Wire Implant
P/N N/A

Testing Initiated: (b)(4)
Testing Completed

(b)(4)

PREPARED FOR

Stimwave Technologies, Inc.
9375 E. Shea Blvd, Suite 147
Scottsdale, AZ 85260

PERFORMED BY

(b)(4)

Contents

(b)(4)

4.0 Materials and Equipment

(b)(4)

5.0 Experimental Design

(b)(4)

(b)(4)

5.2 General Description of Experiment

(b)(4)

6.0 Experimental Procedures

(b)(4)

7.0 Data Analysis Techniques

(b)(4)

8.0 Expected Results and Conclusions

(b)(4)

(b)(4)

REPORT
Evaluation of Magnetic Field Interactions, Heating, and Artifacts for the Freedom-4 Lead (10-cm version)

(b)(4)

Presented to:

Laura Tyler Perryman, MS, MBA, PMP, CSM
Founder and Executive Director
Stimwave Technologies, Inc.
9375 E. Shea Blvd., Suite 147
Scottsdale, AZ 85260

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

Assessment of MRI Issues for a 3-T "Immune" Programmable CSF Shunt Valve

(b)(4)

(b)(4)

REPORT
Tests Performed to Determine the Effects of Exposures to 1.5-Tesla/64-MHz MRI Conditions on Freedom-4 Leads

(b)(4)

Presented to:

Laura Tyler Perryman, MS, MBA, PMP, CSM
Founder and Executive Director
Stimwave Technologies, Inc.
9375 E. Shea Blvd., Suite 147
Scottsdale, AZ 85260

(b)(4)

(b)(4)

REPORT
Tests Performed to Determine the Effects of Exposures to 3-Tesla/128-MHz MRI Conditions on Freedom-4 Leads

(b)(4)

Presented to:

Laura Tyler Perryman, MS, MBA, PMP, CSM
Founder and Executive Director
Stimwave Technologies, Inc.
9375 E. Shea Blvd., Suite 147
Scottsdale, AZ 85260

(b)(4)

(b)(4)

Assessment of MRI Issues for a 3-T "Immune" Programmable CSF Shunt Valve

(b)(4)

(b)(4)

Test Report

Preconditioning and Thermal Shock Test

(b)(4)

(b)(4)

(b)(4)

RF Heating and Potential for Unintended Stimulation of the Stimwave lead during MRI

(b)(4)

ADMINISTRATIVE DATA

1.	**PURPOSE OF TESTS:**	To perform tests on Medical Units P/N WAA-A001 in accordance with the procedures and specifications cited herein.
2.	**CUSTOMER:**	Stimwave Technologies, Inc.
3.	**DESCRIPTION OF TEST ITEMS:**	Medical Units
4.	**PART NUMBER:**	(b)(4)
5.	**SERIAL NUMBER(S):**	
6.	**REFERENCES:**	
7.	**QUANTITY OF ITEMS TESTED:**	
8.	**SECURITY CLASSIFICATION:**	
9.	**DATE TEST COMPLETED**	
10.	**TESTS CONDUCTED BY:**	
11.	**DISPOSITION OF TEST ITEMS:**	
12.	**TEST ABSTRACT:** Drop,Impact,Push Dust, Water/Splashing, Atm Pressure Hot Humid,Low Temp,Mold Stress Relief	
13.	**STANDARD TEST CONDITIONS:**	
14.	**SOURCE INSPECTION:**	
15.	**PURCHASE ORDER NUMBER:**	
16.	**GOVERNMENT CONTRACT NO. :**	

(b)(4)

(b)(4)

TEST REPORT (b)(4)
of Medical Units
P/N WAA-A001

Testing Initiated: (b)(4)
Testing Completed

(b)(4)

PREPARED FOR

Stimwave Technologies, Inc.
9375 E. Shea Blvd, Suite 147
Scottsdale, AZ 85260

PERFORMED BY

(b)(4)

(b)(4)

Tissue depth study for a fully implantable, remotely powered and programmable wireless neural stimulator

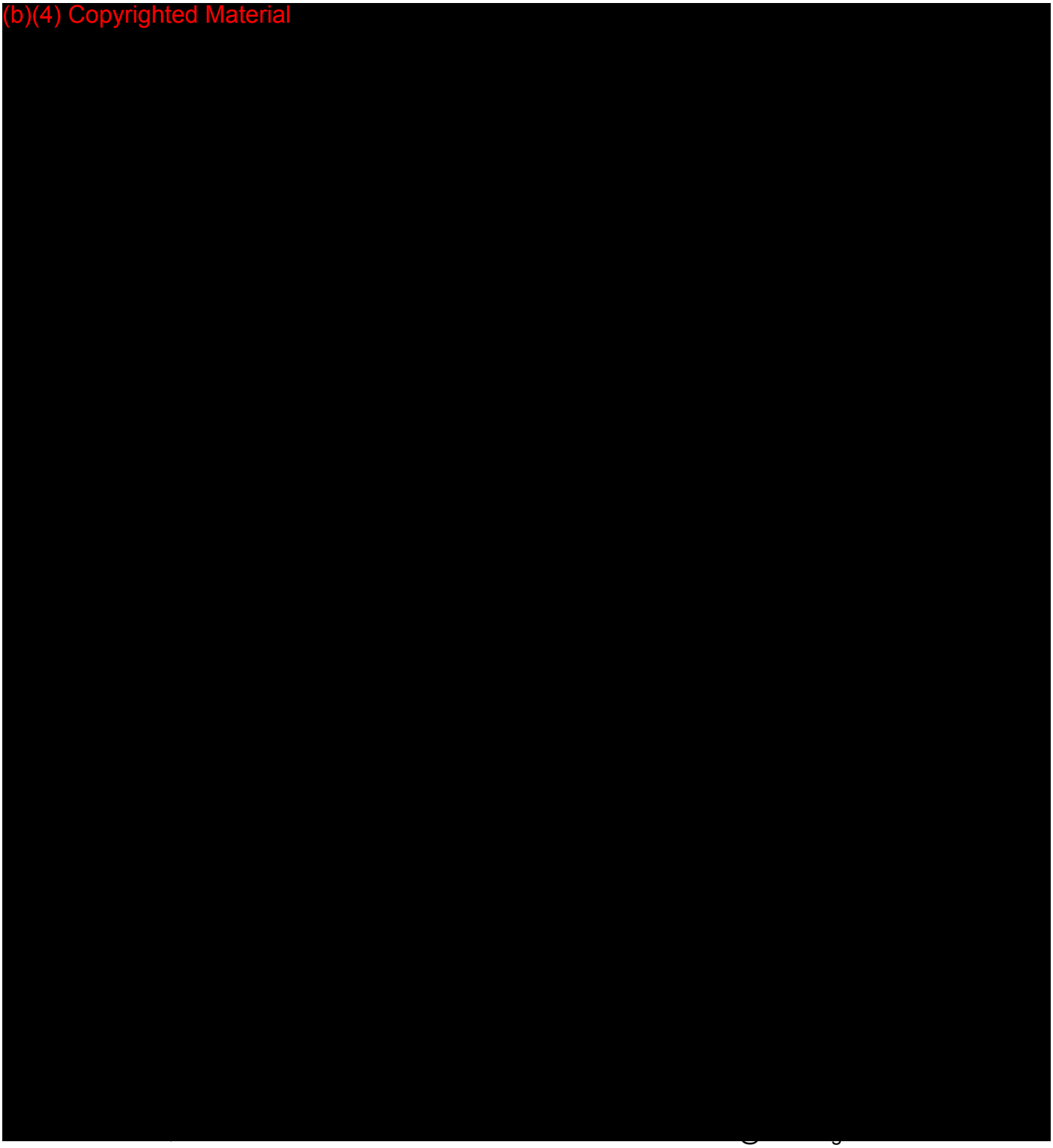
This clinical evaluation is focused on relevant scientific literature available in the public domain that relates to equivalent, commercially available spinal cord stimulation devices used to provide relief from chronic, intractable pain of the trunk and/or limbs, considering safety, performance, design characteristics, and intended purpose. A systematic literature search has been conducted in accordance with the Literature Search Protocol.

(b)(4)

(b)(4)

Pain

Epidural Spinal Cord Stimulation for Treatment of Chronic Pain—Some Predictors of Success. A 15-Year Experience



(b)(4)

(b)(4) Copyrighted Material \ Journal Data

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Copyrighted
Material \
Journal Data

Injectable spinal cord stimulator system: Pilot study

(b)(4) Copyrighted Material \ Journal Data

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Response:

(b)(4)

[redacted]

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Response:

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[redacted]

Response:

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[redacted]

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(b)(4)

K141399/S001

Stimwave Technologies Incorporated
420 Lincoln Road
Suite 365
Miami Beach, Florida 33139

September 5, 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K#141399.S001

Dear Sir or Madam:

The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy.

Kind Regards,

Elizabeth Greene

(b)(4)

(b)(4)

stim wave TECHNOLOGIES

FREEDOM SPINAL CORD STIMULATOR

WEARABLE ANTENNA ASSEMBLY

USER MANUAL

Caution: Federal law restricts this device to sale by or on the order of a physician.

MODEL: WAA-A012

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE LABELING

Refer to the appropriate product for symbols that apply.

Manufacturer

Consult instructions before use

Type BF applied part

The use of this device might be subject to individual country licensing regimes in Europe

Lot number

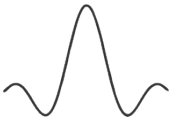
Caution

European Authorized Representative

Warning

Do not dispose of the Wearable Antenna Assembly

MR Unsafe

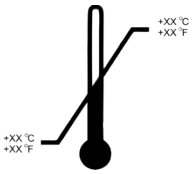


Carrier Frequency Center

Non-ionizing electromagnetic radiation

Store in a cool, dark, dry place

This device meets the electromagnetic interference limits approved by the Federal Communications Commission.



Temperature limitations

This device complies with Part 15 and 18 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

TABLE OF CONTENTS

HOW TO USE THIS MANUAL

This manual will help you understand how to use and care for your neurostimulator system. It also provides you with warnings and precautions you should know about. You should discuss with your clinician any questions or concerns you have after reading this manual. Refer to the Freedom Product Safety Guide to learn about EMC related safety information.

SAFETY INFORMATION

INDICATIONS FOR USE

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

CONTRAINDICATIONS

- **Poor surgical risks –** Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Freedom Stimulator or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the stimulator or WAA and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Users who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the Freedom SCS System. The energy in high-level areas can be transferred through the stimulator and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:
    - Radio or cell phone transmission stations

  - Facilities using radiofrequency heat sealers or induction heaters
  - Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the Freedom SCS System may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Freedom SCS System is being affected by EMI then you should:

- Immediately move away from the equipment or object.
- Remove the external transmitting device (the Wearable Antenna Assembly (WAA) from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation.
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics.

- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics.
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment.
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals.

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS System. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Stimulator fracture – If the stimulator insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.

When electrocautery is necessary, these precautions must be followed:

- The WAA should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the stimulator.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the stimulator is working as intended.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS System with other active implantable or body worn medical devices. These devices include other neurostimulators, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic resonance imaging (MRI) – An MRI examination may be safely performed under certain specific conditions. Refer to the Product Safety Guide for specific MRI guidelines.

The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, and in the process cause serious harm to the patient or other people or damage to the MR system.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Making sure that the X-ray beam does not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the WAA and turn on stimulation.
- Check for proper stimulation, and that indicator lights are operating as expected.
- Shut off the WAA if it is suspected that the device is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a stimulator. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the stimulator. If RF ablation is used, ensure that ablation is not performed over or near the stimulator.

Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with a limited number of security systems, and have demonstrated that the Freedom SCS System (implanted device and WAA) are not affected by close proximity of the security systems. Any security system may temporarily interrupt spinal cord stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels an increase in stimulation near a security system, they promptly move away from the area and remove the WAA from the body.

When possible, it is best to avoid these security systems or to remove the WAA off while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Induced electrical currents can cause heating that may result in tissue damage.

High-output ultrasonics / lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS System. Use of lithotripsy may result in damage to the device or harm to the patient.

Bone growth stimulators – Safety has not been established for magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the Freedom SCS System. Use of dental drills or ultrasonic probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of the Freedom SCS System. Use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers within the vicinity of the Freedom SCS System. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with the Freedom SCS System. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with the Freedom SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the stimulator site. Magnetic fields will generally not affect the stimulator.

WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

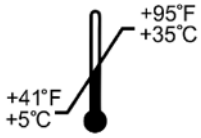
PRECAUTIONS

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal procedures and should review the procedures described in the Instructions for Use.

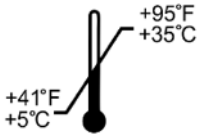
Keep the WAA dry – The WAA is not waterproof. Keep it dry to avoid damage. Do not use the WAA when engaging in water activities.

Storage temperatures – The Freedom SCS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact Stimwave if a storage temperature is surpassed.

Freedom Stimulator
Storage Temperature



Wearable Antenna Assembly
Storage Temperature



Clean the WAA – Clean the outside of the WAA with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the WAA with care – The WAA is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the WAA out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Airline policies - Follow airline policies for use of medical spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

Use the WAA as directed – Use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

Do not dismantle the WAA – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

Use of another patient's WAA - Never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your stimulator to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System. However, take care to not put undue stress on the device. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your amplitude to the lowest setting and turn OFF your System before engaging in activities that could become unsafe. Discuss these activities with your clinician.

ADVERSE EVENT SUMMARY

Implantation of a spinal cord stimulation system is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material
- Infection
- Leakage of cerebrospinal fluid
- Epidural hemorrhage, hematoma, or paralysis

Therapeutic use of the Freedom SCS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation
- Stimulator migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning system

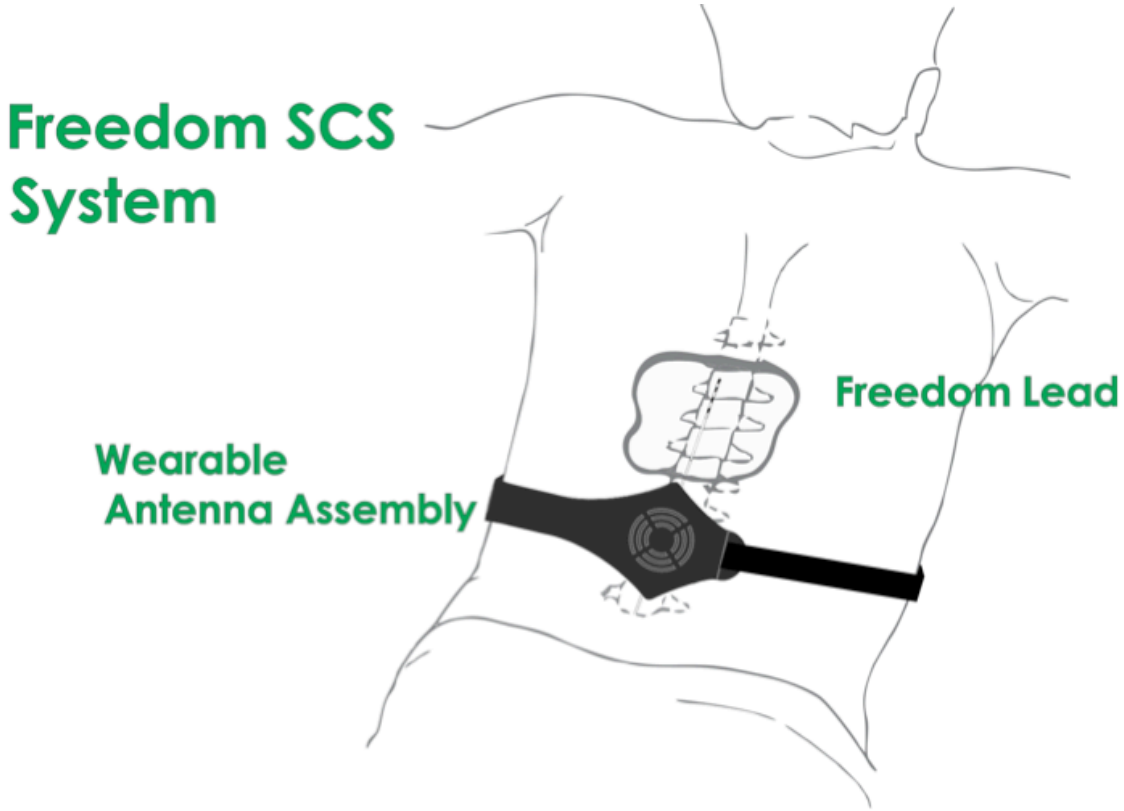
Adverse events that could occur with the Freedom SCS System:

- Stimulator migration, resulting in altered stimulation therapy that may be uncomfortable
- Stimulator fracture, resulting in loss of stimulation
- Infection, resulting in tissue sensitivity, redness and swelling

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Contact your clinician immediately if you experience any problems. Over time there could be changes in the level of pain control. Contact your clinician if you experience a change in stimulation that you believe is a result of the stimulator slipping from the implant site.

USING YOUR WEARABLE ANTENNA ASSEMBLY

HOW THE WEARABLE ANTENNA ASSEMBLY WORKS



Freedom Stimulator – Also known as an "implant" or "electrode", the Stimulator contains the neurostimulator. The Stimulator is a set of thin wires and a miniature receiver, covered with a protective casing. The neurostimulator has small metal electrodes near the tip. An electrical field of energy is created when power is applied to the electrodes. The electrical field aids in blocking the pain signals coming from certain nerves of the spinal cord. The neurostimulator receives energy wirelessly from an external unit.

Wearable Antenna Assembly (WAA) – The WAA is an electronic device used to power the Stimulator. Wireless power is sent from the WAA and through your skin to the Stimulator. The WAA is worn around your midsection over top of the area where the Stimulator(s) is implanted.

USING YOUR WAA

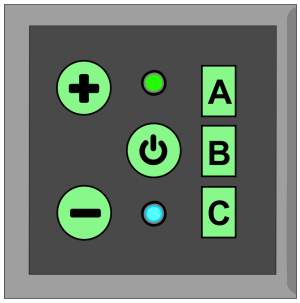
HOW THE WAA WORKS

The WAA communicates with your neurostimulator by sending radiofrequency signals. Your neurostimulator only accepts communication from your WAA. The clinician programs your WAA with your specific stimulation parameters. A Bluetooth® connection is made in order to program your WAA.

OVERVIEW OF WAA

1. Elastic Belt Attachment – Used to connect one end of the elastic belt to the WAA.
2. Non-Replaceable Battery – A built in battery that cannot be replaced.
3. User Controls –Controls used to turn the power on/off and adjust parameter settings.
4. Antenna – A built in antenna that is aligned to your lower back area.
5. Elastic Belt Attachment – Used to connect one end of the elastic belt to the WAA.

OVERVIEW OF THE USER CONTROLS

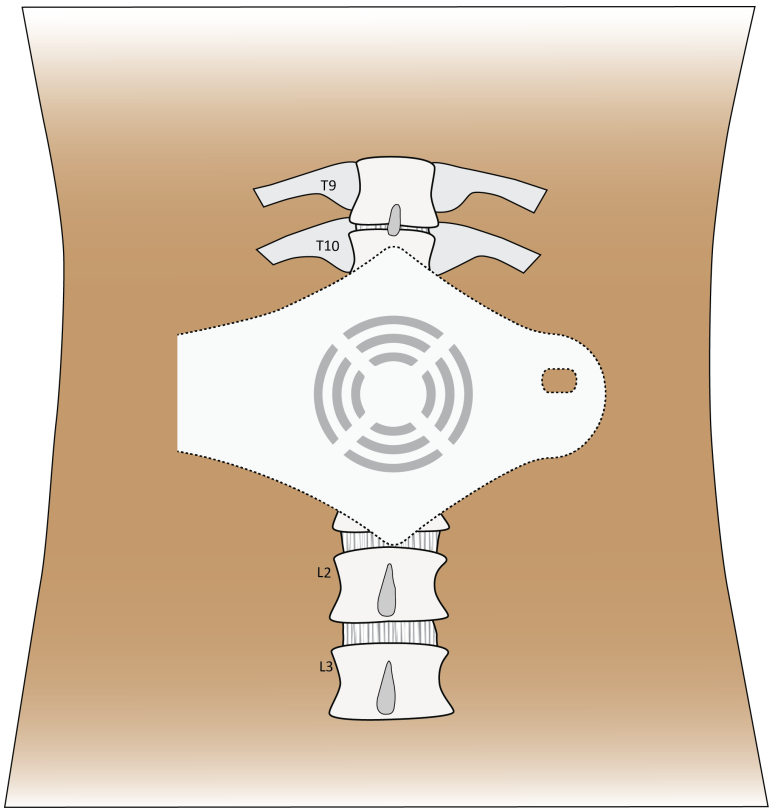


Key	Action
	Power ON/OFF Key – Used to turn the WAA "ON" or "OFF".
	Increase Amplitude Key– Used to increase the stimulation strength in 0.5 mA increments.
	Decrease Amplitude Key– Used to decrease the stimulation strength in 0.5 mA increments.
	Power Indicator Light – A green light used to identify the status of the WAA. The light blinks when the system is "ON".
	Charging Indicator Light – A blue light used to identify the battery status when the WAA is charging. The light is on while the battery is charging. The light blinks when the system has reached full battery capacity.
	Program Selection Keys – Used to select a set of stimulation parameters pre-programmed by your clinician.

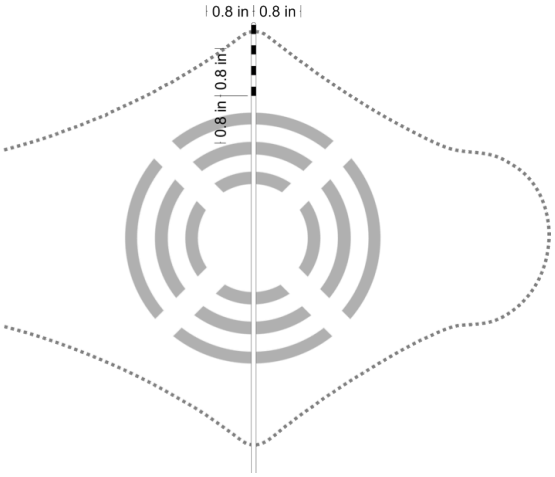
POSITIONING THE WAA

The WAA must be placed over the general region of the implanted receiver within the Stimulator body in order to transfer the optimal amount of power to the device. To place the WAA, attach the WAA band around your midsection with the antenna portion directly in the middle of your lower back. Ensure that the WAA is placed overtop of a thin layer of clothing. Do not place directly on your skin. Refer to the following illustrations for the best location to wear the WAA. Work with your clinician to find the optimal location for the most effective therapeutic relief.

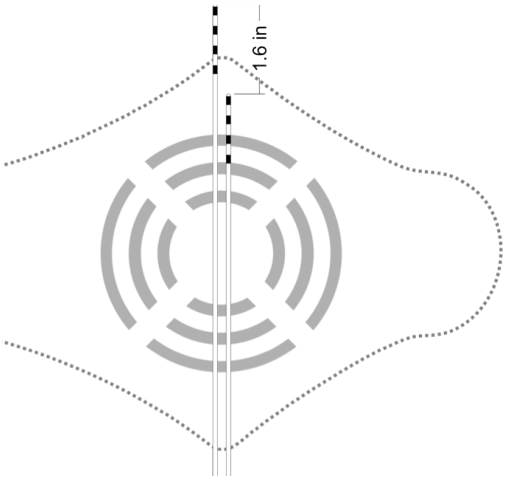
> ⚠ WARNING:
>
> Do not place the WAA directly on your skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.



This figure illustrates the optimal position of the WAA over your back. Align the antenna directly over the center of your spine. You may need to adjust the position up or down depending on where your stimulator is located.



This figure illustrates the optimal position of the WAA over one Stimulator.



This figure illustrates the optimal position of the WAA over two vertically spaced Stimulators.

TURNING THE WAA "ON" AND "OFF"

Complete the following steps to turn the WAA "ON" or "OFF".

1. Press and hold the Power ON/OFF Key until the green Power Indicator Light activates.

NOTE: *The WAA automatically starts at the lowest amplitude setting when turned on.*

> ⚠ CAUTION:
>
> If any discomfort that is attributed to stimulation is ever experienced, turn off the WAA and/or remove the WAA from the body.

STARTING STIMULATION AND POWERING THE NEUROSTIMULATOR

Complete the following steps to power the stimulator and provide stimulation.

1. Turn on the WAA.
2. Use the Program Selection Keys to select pre-programmed stimulation settings.
3. Place the WAA directly over top of the neurostimulator.
4. Use the Increase Amplitude Key and Decrease Stimulation Key to adjust the stimulation amplitude as directed by your clinician.

ADJUSTING YOUR STIMULATION

To receive the most effective therapy you will need to adjust your stimulation throughout the day. Your clinician will provide guidelines about when you may want to adjust your stimulation. Table 1 provides general guidelines on how to adjust your stimulation.

Table 1: General guidelines on how to adjust your stimulation.

Situation	Action
Stimulation is too strong	Decrease amplitude with the Decrease Stimulation Key
Stimulation is not strong enough	Increase amplitude with the Increase Stimulation Key
You have unexpected changes in stimulation	1. Remove the WAA 2. Decrease amplitude 3. Put the WAA on your body 4. Adjust amplitude to the desired level
You have tried adjusting stimulation but are unable to find an effective setting	Contact your clinician
You will be passing through a security device	Turn off stimulation Remove the WAA
You will be using potentially dangerous equipment	
You will be having a medical procedure	

INCREASING OR DECREASING STIMULATION AMPLITUDE

Complete the following steps to adjust the stimulation amplitude:

1. Press the "Up" arrow key to increase the amplitude by 0.5 mA.
2. Press the "Down" arrow key to decrease the amplitude by 0.5 mA.

NOTES:

- *The WAA must be turned on to increase or decrease the amplitude.*
- *The WAA does not need to be placed over the stimulator to change amplitude.*

△CAUTION:

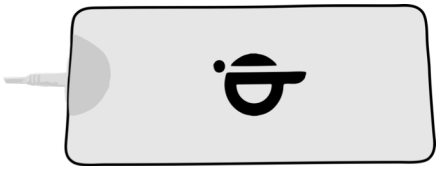
Turn the power off or decrease the amplitude before changing the position of the WAA. Do this to prevent possible uncomfortable or unexpected stimulation.

MAINTENANCE

BATTERY CHARGING

Follow these guidelines to recharge the battery pack in the WAA. You will need the Charging Pad to recharge the internal battery. See Table 2 for common questions about battery charging. Follow these instructions to charge your WAA:

1. Plug the Charging Pad into a wall outlet.
2. Remove the WAA from your midsection.
3. Place WAA face up on the charging platform.
4. WAA may be rotated in any direction and still effectively charge.
5. Charging Indicator Light will stay on while the battery is charging.
6. Allow the battery to charge for at least four (4) hours.
7. Charging Indicator Light will blink when the battery is fully charged.
8. WAA is now ready to be used again.

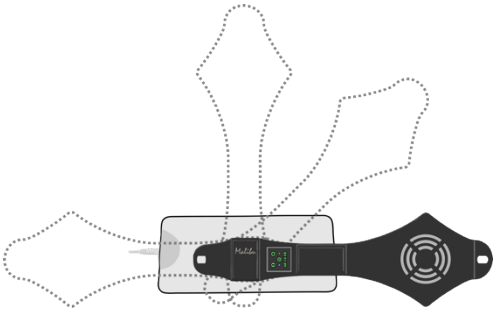


> ⚠ WARNING:
>
> Do not use or wear the WAA while the device is charging. Wearing the WAA while the device is charging may cause harm to you or the system. The WAA will not transmit stimulation while the device is charging.

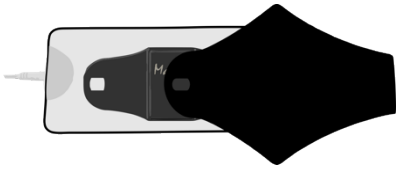
NOTE: The battery is built into the WAA. The battery does not need to be removed. Contact your clinician if you experience poor battery life.

Table 2: Common questions about battery charging.

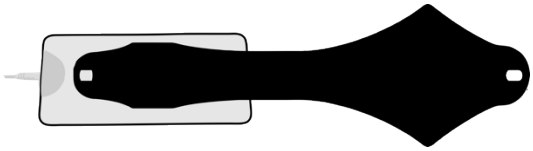
Common Questions	Response
How long will it take to recharge a "dead" or depleted battery?	It normally takes an average of four (4) hours to recharge the battery.
When is the battery near depletion, and how will I know?	The WAA will turn off and not respond to user controls when near depletion. The indicator lights will not turn on. You should place the WAA on the charger pad as illustrated above.
How long will a fully charged battery provide power?	Nine (9) hours on average. The battery performance is affected by the amount of total power used on average.
When is the battery done charging?	The WAA is done charging when the Charging Indicator Light (blue) begins to blink.



WAA must be placed face up on the charging pad. WAA may be rotated any direction and still effectively charge.



WAA may be folded over top of itself and still charge.



WAA may **NOT** be placed face down on the charging pad. The battery will not recharge in this position.

CLEANING AND CARE PRECAUTIONS

Follow these guidelines to ensure that the WAA function properly:

- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Keep the device out of the reach of children and pets.
- Use the device only as explained to you by your clinician or as discussed in this manual.
- Handle the device with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the device.

SAFETY AND TECHNICAL CHECKS

Periodic safety checks or maintenance of the WAA are not required. The WAA contains no user-serviceable parts. If repair or service is needed, contact your clinician or a Stimwave representative for a replacement. Refer to the contact information at the end of this manual.

WAA DISPOSAL

The WAA should be returned to your clinician or a Stimwave representative. Do not dispose of your WAA in the garbage.

TROUBLESHOOTING

This information can help you to solve problems that may arise with the WAA. It also provides information on when to call your clinician. See Table 3 for a list of common problems and actions to remedy the issue.

NOTE: *If a problem is not solved after several attempts, or if a problem is not described here, contact your clinician or Stimwave representative.*

Table 3: Problems you may experience along with potential causes and actions to remedy the issue.

Problem	Causes and Actions
Uncomfortable stimulation: You are too uncomfortable with the current stimulation to think about how to change it.	The selected parameter settings are not suitable for your activity or posture. • Reduce the amplitude on the WAA. • Remove the WAA from your body.
Intermittent stimulation: You feel stimulation only some of the time.	The WAA may have a poor connection with the implant. The antenna may not be placed over the area of the implanted receiver. • Place the antenna directly over the stimulator. • If you are not receiving adequate pain relief, contact your clinician or Stimwave.
No stimulation: You do not feel stimulation but you think stimulation should be on.	Stimulation is off. • Turn the power OFF and wait 5 seconds before turning the power back ON. The antenna is not placed over the stimulator. • Place the antenna directly over the stimulator. The amplitude of the WAA is set too low to feel. • Increase the amplitude.
The WAA is unresponsive: The indicator light does not turn on. The stimulation amplitude keys do not respond.	The WAA is not powered on. • Turn the power ON. The WAA system has "frozen". • Turn the power OFF and wait 5 seconds before turning the power back ON. The battery is not charged. • Recharge the battery by placing the WAA on the charger.
Dropped WAA: Your WAA falls off a cabinet or table.	WAA is designed to withstand a short drop on a hard surface and still operate normally. Try powering ON the WAA and allow it to transmit for 10 minutes while not worn on the body. If the WAA appears to be functioning properly, try using it.
Fluid on the WAA: Fluid was spilled onto the WAA or the WAA was dropped into water.	The WAA is not waterproof, and water can damage the device. • Immediately remove the WAA from the water, then dry the WAA with a towel damped with clean tap water. Unplug the power cord and allow the WAA to dry at room temperature for 24-48 hours.

SPECIFICATIONS

Table 4: Specifications of the WAA.

Item	Specification
Amplitude	0 to 15 mA
Pulse Width	50 to 500 µs
Frequency (of therapy)	2 to 1500 Hz
Number of Channels	1
Number of Programs	3
Charging Pad Power Source	120-240V 50-60 Hz power line
Operating and Storage Temperature, relative humidity	10º C to 55º C (50º F to 131º F), 20% to 90%
Operating/storage atmospheric pressure	70kPa to 106 kPa (20.7 in Hg to 31.3 in Hg)
Size (approximate)	45 cm x 9.4 cm x 4 cm (24 in x 3.7 in x 1.6 in)
Weight (approximate)	0.5 kg (1 lb.)
WAA Material (Do not place directly on skin, to be worn over a thin layer of clothing at all times)	Polyurethane

Table 5: Specifications of the Battery Charger.

Parameter	Min	Typical	Max	Units
Supply Voltage	120	---	240	$V_{A/C}$
Supply Voltage Frequency	50	---	60	Hz
Inductive Power Transmission Frequency	100	---	205	KHz
Input Voltage (DC)	18.5	19	19.5	V
Input Current	---	---	400	mA
Standby (Average) Current	---	---	20	mA
Output Power	5	---	---	W
Reaction Temperature	-10	---	40	°C
Working Heat Up Range	---	---	20	°C
Working Ambient Humidity	---	---	80	%
Power Transfer Efficiency	---	78	---	%
Battery Recharge Time (assuming 3.7V battery)	2	3	8	hours
Modulation	---	CW	---	N/A

WIRELESS INFORMATION

The Freedom SCS System uses wireless technology to program the WAA and to power the stimulator. The WAA is programmed utilizing a Bluetooth® data communication protocol. Bluetooth® is used only during programming sessions and only by a trained clinician. Programs are stored on the WAA, which can then be used on a daily basis. The WAA communicates with the stimulator using a pulsed radio frequency signal centered at a frequency of 915 MHz.

Wireless Specifications	
Transmission Frequency of WAA	915 megahertz (MHz)
Bandwidth of WAA	149 kilohertz (kHz)
Power Output of WAA	15 watts (W) peak or 1.1 watt (W) average power: Pulse-Amplitude Modulation (PAM) and Pulse-Width Modulation (PWM)
WAA Tissue penetration depth	Up to 4 inches or 10 cm
Quality of Service	In order for the Freedom SCS System to operate, the WAA must be in close range of the Stimulator. The WAA should be centered over the Stimulator within 0.8 inches or 2 cm. To better ensure proper function, the WAA should be worn in the same position as when it was originally fitted. When the wireless link between the WAA and Stimulator is broken, stimulation will cease. The wireless link may not function in the presence of large magnetic or radio fields.
Frequency of Bluetooth®	2.4 gigahertz (GHz)
Bandwidth of Bluetooth®	900 kHz
Power of Bluetooth®	2.5 milliwatt (mW)
Bluetooth® Operating Distance	4 to 5 meters
Wireless Link Performance	Wireless link active less than 10% of the time when the WAA is approximately 1 inch or closer to the implant.
Wireless Security	The Stimulator will only operate if it is within a very short distance of the WAA and such communication is disabled when Bluetooth® is enabled. The WAA uses encryption and proprietary data protocols to reduce the likelihood of inadvertent control or malicious "hacking" of the System through Bluetooth®. Only the iPad Malibu Application is able to communicate with the WAA via Bluetooth®. No identifiable personal data is stored or transmitted by the WAA.
Bluetooth Quality of Service	Typical Bitrate: 360 bps Maximum Data Latency: 100ms Maximum Operating Distance: 4 to 5 meters

GLOSSARY

Amplitude – The strength of the stimulation. It affects the stimulation strength or coverage required to manage your pain. This is the only setting that you as a patient have the ability to adjust. Amplitude is measured in milliamps (mA).

Caution – A statement or picture that describes actions that potentially result in damage or improper functioning of a device.

Clinician – A general term used for healthcare professionals such as a doctor or nurse.

Contraindication – A condition or circumstance when a person or patient should not have a device.

Electrode – A piece of metal near the distal (far) end of the spinal cord stimulator. The electrode(s) are the functional part of the device that delivers electrical power to your nerves.

Electromagnetic interference (EMI) – A strong field of energy near electrical or magnetic devices that could prevent the stimulator from functioning properly.

Frequency – The number of pulses delivered per second, and is also called pulse rate. Rate can feel like "tapping" if the frequency is set low.

Indication – The purpose of the neurostimulation system and the medical condition for which it may be implanted.

Neurostimulation system – The implanted and external components of the system that are required in order for the system to function appropriately.

Parameter – One of three stimulation settings that adjust the electrical pulse: amplitude, pulse width, and frequency.

Program – A set of pre-programed therapy parameters including frequency and pulse width. Your clinician or Stimwave representative will set these programs and explain how to use them.

Pulse Width – The duration of the pulse. It affects the shape of the waveform that is applied and the selection of certain types of nerve fibers that are blocked by the electric field.

Spinal cord – A main part of the central nervous system that is composed of nerve tissue, which act as a main pathway between the brain and the body.

Stimulation settings – Refers to all the features available to define the stimulation delivered.

Therapy – Treatment of a disease or condition.

Warning – A statement describing an action or situation that could harm the patient.

CONTACT INFORMATION

MANUFACTURER

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stim wave TECHNOLOGIES

FREEDOM SPINAL CORD STIMULATOR SYSTEM

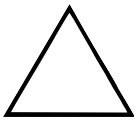
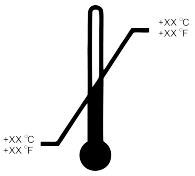
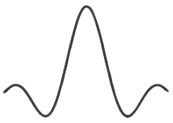
PRODUCT SAFETY GUIDE

Caution: Federal law restricts this device to sale by or on the order of a physician.

MODEL NUMBERS: FRT4-A001, FRE4-A001, WAA-A012

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

	Device reference identification		Consult instructions before use
	Lot number		Store in a cool, dark, dry place
	Quantity of product included in package		Caution
	Manufacturer		Warning
	Do not dispose of the Wearable Antenna Assembly		MR Conditional
	Non-ionizing electromagnetic radiation		MR Unsafe
	Temperature limitations		Type BF applied part
	Carrier Frequency Center		This device meets the electromagnetic interference limits approved by the Federal Communications Commission.

This device complies with Part 15 and 18 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

TABLE OF CONTENTS

HOW TO USE THIS MANUAL

Use this manual before or during use of your spinal cord stimulator. This manual will describe how stimulation works. It also provides you with warnings and precautions you should know about. You should discuss with your clinician any questions or concerns you have after reading this manual. Refer to the Wearable Antenna Assembly User Manual to learn how to operate the controls of the Freedom Spinal Cord Stimulator (SCS) System.

SAFETY INFORMATION

INDICATIONS FOR USE

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

CONTRAINDICATIONS

- **Poor surgical risks –** Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Freedom Stimulator or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the stimulator or WAA and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Users who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the Freedom SCS System. The energy in high-level areas can be transferred through the stimulator and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:

- Radio or cell phone transmission stations
- Facilities using radiofrequency heat sealers or induction heaters
- Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)

- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the Freedom SCS System may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Freedom SCS System is being affected by EMI then you should:

- Immediately move away from the equipment or object.
- Remove the external transmitting device (the Wearable Antenna Assembly (WAA) from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics

- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS System. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Stimulator fracture – If the stimulator insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.

When electrocautery is necessary, these precautions must be followed:

- The WAA should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the stimulator.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the stimulator is working as intended.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS System with other active implantable or body worn medical devices. These devices include other neurostimulators, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic resonance imaging (MRI) – An MRI examination may be safely performed under certain specific conditions. Refer to the MRI Safety Information section of this manual for specific MRI guidelines.

The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, and in the process cause serious harm to the patient or other people or damage to the MR system.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Making sure that the X-ray beam does not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the WAA and turn on stimulation.
- Check for proper stimulation, and that indicator lights are operating as expected.
- Shut off the WAA if it is suspected that the device is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a stimulator. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the stimulator. If RF ablation is used, ensure that ablation is not performed over or near the stimulator.

Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with a limited number of security systems, and have demonstrated that the Freedom SCS System (implanted device and WAA) are not affected by close proximity of the security systems. Any security system may temporarily interrupt spinal cord stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels an increase in stimulation near a security system, they promptly move away from the area and remove the WAA from the body.

When possible, it is best to avoid these security systems or to remove the WAA off while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Induced electrical currents can cause heating that may result in tissue damage.

High-output ultrasonics / lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS System. Use of lithotripsy may result in damage to the device or harm to the patient.

Bone growth stimulators – Safety has not been established for magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the Freedom SCS System. Use of dental drills or ultrasonic probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of the Freedom SCS System. Use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers within the vicinity of the Freedom SCS System. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with the Freedom SCS System. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with the Freedom SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the stimulator site. Magnetic fields will generally not affect the stimulator.

WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

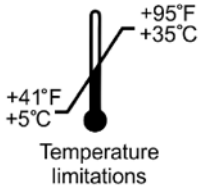
PRECAUTIONS

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal procedures and should review the procedures described in the Instructions for Use.

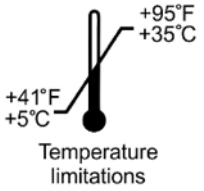
Keep the WAA dry – The WAA is not waterproof. Keep it dry to avoid damage. Do not use the WAA when engaging in water activities.

Storage temperatures – The Freedom SCS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact Stimwave if a storage temperature is surpassed.

Freedom Stimulator
Storage Temperature



Wearable Antenna Assembly
Storage Temperature



Clean the WAA – Clean the outside of the WAA with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the WAA with care – The WAA is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the WAA out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Airline policies - Follow airline policies for use of medical spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

Use the WAA as directed – Use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

Do not dismantle the WAA – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

Use of another patient's WAA - Never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your stimulator to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System. However, take care to not put undue stress on the device. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your amplitude to the lowest setting and turn OFF your System before engaging in activities that could become unsafe. Discuss these activities with your clinician.

ADVERSE EVENT SUMMARY

Implantation of a spinal cord stimulation system is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material
- Infection
- Leakage of cerebrospinal fluid
- Epidural hemorrhage, hematoma, or paralysis

Therapeutic use of the Freedom SCS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation
- Stimulator migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning system

Adverse events that could occur with the Freedom SCS System:

- Stimulator migration, resulting in altered stimulation therapy that may be uncomfortable
- Stimulator fracture, resulting in loss of stimulation
- Infection, resulting in tissue sensitivity, redness and swelling

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Contact your clinician immediately if you experience any problems. Over time there could be changes in the level of pain control. Contact your clinician if you experience a change in stimulation that you believe is a result of the stimulator slipping from the implant site.

MRI SAFETY INFORMATION

Magnetic resonance imaging (MRI) may be safely performed under certain conditions on a patient with a single Freedom Stimulator. In-vitro testing demonstrated that the Freedom Stimulator is MR Conditional. All other components of the Freedom SCS System are MR Unsafe, and must not be allowed in the MR system room (i.e., these components must be removed from the patient or are not allowed in the MR system room). Freedom System components are labeled as follows:

 MR Conditional Component	 MR Unsafe Components
• Freedom-4 Stimulator (Receiver Only). A patient with the Freedom-4 Stimulator may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. See specific conditions for safe scanning given below.	• Freedom-4 Stimulator (Trial Stimulator) • Wearable Antenna Assembly • Programmer • Wireless Charging Pad • Needles • Guidewire • Stylets

The WAA **MUST NOT** be present in the MR system room at **ANY TIME**. Failure to adhere to the specific requirements described in this manual can result in tissue damage, severe injury, or death. Please use the contact information found on the last page of this manual for additional information.

DO NOT have an MRI examination while the trial stimulator is implanted. The trial stimulator is MR Unsafe. Only the receiver stimulator for chronic use is MR Conditional.

Follow these instructions when preparing for an MRI examination:

- Bring your current patient ID card to every MRI appointment.
- Show the MRI personnel your patient ID card. This indicates that the manufacturer of your System is Stimwave Technologies. The ID card also identifies your System model number.

The MRI personnel can use this information to obtain instructions to determine the eligibility of your System for the MRI procedure. Safe MR conditions can then be used.

⚠ WARNING:

Remove the Wearable Antenna Assembly from the patient before entering the MR system room. The strong magnetic field of the MR system could attract or otherwise damage the unit and in the process cause serious harm or damage to the MR system.

PREPARATION FOR AN MRI

The following steps must be performed prior to an MRI on a patient with an implanted Freedom Stimulator.

1. Allow at least six weeks from the date of implantation to the time of the MRI.
2. Remove the WAA (the external component of the Freedom System) from the patient before allowing the patient to enter the room where the MRI procedure will take place.
3. Do not conduct an MRI procedure if the patient has any other implant or health condition that prohibits or contraindicates an MRI examination.
4. Instruct the patient to immediately inform the MRI system operator (i.e., the MRI technologist) if any discomfort, stimulation, shocking, or heating occurs during the examination.
5. The patient must be conscious during the MRI in order to be able to inform the MRI operator of any problems.
6. Verify with the MRI operator that all proposed MRI conditions comply with the requirements specified in this manual. If any MRI parameter is not met and cannot be modified, do not perform the MRI procedure.

MRI CONDITIONS MR

NOTE: *This information applies only to cases where a single Freedom Stimulator is implanted.*

The MRI scan sequences must meet the following conditions. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer. If the MRI scan sequences do not meet the conditions, then the pulse parameters must be adjusted so that they comply.

Non-clinical testing has demonstrated the Freedom Stimulator is MR Conditional. The Freedom Stimulator can be scanned safely under the following conditions.

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Maximum spatial gradient field of 30 T/m (3,000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of continuous scanning.
- No restrictions on position of the Freedom Stimulator with respect to MR system bore or body part undergoing MR imaging.
- No other components of Freedom SCS System (e.g. WAA, wireless charging pad, needle, stylets, guidewire) may be taken into the MR system room.
- No restrictions on use of transmit RF coils.

NOTE: *Enter the patient's weight into the MR system console to ensure that the whole body averaged specific absorption rate (SAR) is estimated correctly.*

Under the scan conditions defined above, the Freedom Stimulator is expected to produce a maximum temperature rise of 2.3ºC in a 1.5-Tesla/64-MHz system or 1.9ºC in a 3-Tesla/128-MHz system after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact extends approximately 15 mm from the device when imaged with a gradient echo pulse sequence and a 3 Tesla/128-MHz MRI system.

DURING AN MRI EXAMINATION

The patient should be conscious during the MRI procedure. Monitor the patient both visually and audibly. Check the patient between each MR imaging sequence. Discontinue the MRI examination *immediately* if the patient is unable to respond to questions or reports any problem.

POST-MRI REVIEW

Verify that the patient feels normal. Verify that the Freedom Stimulator is functional by checking its response to the WAA.

ELECTROMAGNETIC ENVIRONMENTS

Guidance and manufacturer's declaration – electromagnetic emissions		
The Freedom SCS System is intended for use in the electromagnetic environment specified below. The user of the System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions, CISPR 11	Group 1	Freedom SCS System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions, CISPR 11	Class B	Freedom SCS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A – System is battery powered	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A – System is battery powered	

Guidance and manufacturer's declaration – electromagnetic emissions			
The Freedom SCS System is intended for use in the electromagnetic environment specified below. The user of the System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/-8kV air	+/- 6kV contact +/-8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2kV power supply lines +/- 1kV input/output lines	N/A – System is battery powered	N/A – System is battery powered
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	N/A – System is battery powered	N/A – System is battery powered
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) 0.5 cycle 40% UT (60% dip in UT) 5 cycles 70% UT (30% dip in UT) 25 cycles < 5% UT (>95% dip in UT) for 5s	N/A – System is battery powered	N/A – System is battery powered
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="4">The Freedom SCS System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150kHz to 80MHz</td><td>N/A – The system has a permanent antenna</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the Freedom SCS System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Filed strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Freedom SCS System is used exceeds the applicable RF compliance level above, the Freedom SCS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Freedom SCS System.
[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distance between portable and mobile RF communications equipment and the Freedom SCS System

The Freedom SCS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Freedom SCS system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

WIRELESS INFORMATION

The Freedom SCS System uses wireless technology to program the WAA and to power the stimulator. The WAA is programmed through a Bluetooth® data communication protocol. Bluetooth® is used only during programming sessions and only by a trained clinician. Programs are stored on the WAA, which can then be used on a daily basis The WAA communicates with the stimulator using a pulsed radio frequency signal centered at a frequency of 915 MHz.

Wireless Specifications	
Transmission Frequency of WAA	915 megahertz (MHz)
Bandwidth of WAA	149 kilohertz (kHz)
Power Output of WAA	15 watts (W) peak or 1.1 watt (W) average power: Pulse-Amplitude Modulation (PAM) and Pulse-Width Modulation (PWM)
WAA tissue penetration depth	Up to 4 inches or 10 cm
Quality of Service	In order for the System to operate, the WAA must be in close range of the Stimulator. The WAA should be centered over the Stimulator within 0.8 inches or 2 cm. To better ensure proper function, the WAA should be worn in the same position as when it was originally fitted. When the wireless link between the WAA and Stimulator is broken, stimulation will cease. The wireless link may not function in the presence of large magnetic or radio fields.
Frequency of Bluetooth®	2.4 gigahertz (GHz)
Bandwidth of Bluetooth®	900 kHz
Power of Bluetooth®	2.5 miliwatt (mW)
Bluetooth® Operating Distance	20 meters or 65 feet
Wireless Link Performance	Wireless link active less than 10% of the time when the WAA is approximately 1 inch or closer to the implant.
Wireless Security	The Stimulator will only operate within a very short distance of the WAA and such communication is disabled when Bluetooth® is enabled. The WAA uses encryption and proprietary data protocols to reduce the likelihood of inadvertent control or malicious "hacking" through Bluetooth®. Only the iPad Malibu Application is able to communicate with the WAA via Bluetooth®. No identifiable personal data is stored or transmitted by the WAA.
Bluetooth Quality of Service	Typical Bitrate: 360 bps Maximum Data Latency: 100ms Maximum Operating Distance: 4 to 5 meters

The Freedom SCS System uses wireless technology to recharge the WAA. The WAA is charged through unidirectional power transfer from the Qi charger (Charging Pad) to the WAA. The Charging Pad utilizes inductive charging and is activated once the WAA is placed on the flat surface of the Charging Pad. Charging stops immediately once the WAA is removed or moved off the Charging Pad. See below for specifications and operational parameters for the Charging Pad.

Parameter	Min	Typical	Max	Units
Supply Voltage	120	---	240	$V_{A/C}$
Supply Voltage Frequency	50	---	60	Hz
Inductive Power Transmission Frequency	100	---	205	KHz
Input Voltage (DC)	18.5	19	19.5	V
Input Current	---	---	400	mA
Standby (Average) Current	---	---	20	mA
Output Power	5	---	---	W
Reaction Temperature	-10	---	40	°C
Working Heat Up Range	---	---	20	°C
Working Ambient Humidity	---	---	80	%
Power Transfer Efficiency	---	78	---	%
Battery Recharge Time (assuming 3.7V battery)	2	3	8	Hours
Modulation	---	CW	---	N/A

GLOSSARY

Amplitude – The strength of the stimulation. It affects the stimulation strength or coverage required to manage your pain. This is the only setting that you as a patient have the ability to adjust.

Caution – A statement or picture that describes actions that potentially result in damage or improper functioning of a device.

Clinician – A general term used for healthcare professionals such as a doctor or nurse.

Contraindication – A condition or circumstance when a person or patient should not have a device.

Diathermy – A medical treatment applied to the outside of the body that delivers energy into the body. Shortwave, microwave, and ultrasound are the three types of energy. Depending on the power level used, diathermy devices may or may not produce heat within the body. Diathermy treatments can be used to relieve pain, stiffness and muscle spasms, reduce swelling, and pain and produce wound healing.

Electrode – A piece of metal near the distal (far) end of the spinal cord stimulator. The electrode(s) are the functional part of the device that delivers electrical power to your nerves.

Electromagnetic interference (EMI) – A strong field of energy near electrical or magnetic devices that could prevent the spinal cord stimulator from functioning properly.

Frequency – The number of pulses delivered per second, and is also called pulse rate. Rate can feel like “tapping” if the frequency is set low.

Indication – The purpose of the neurostimulation system and the medical condition for which it may be implanted.

Neurostimulation system – The implanted and external components of the system that are required in order for the system to function appropriately.

Patient Identification Card – A card that supplies information about the patient, implanted device, and doctor. The card may allow you to bypass security devices.

Parameter – One of three stimulation settings that adjust the electrical pulse: amplitude, pulse width, and frequency.

Program – A set of pre-programed therapy parameters including frequency and pulse width. Your clinician or Stimwave representative will set these programs and explain how to use them.

Pulse Width – The duration of the pulse. It affects the shape of the waveform that is applied and the selection of certain types of nerve fibers that are blocked by the electric field.

Spinal cord – A main part of the central nervous system that is composed of nerve tissue, which act as a main pathway between the brain and the body.

Stimulation – The delivery of electrical power to an area of the body.

Stimulation settings – Refers to all the features available to define the stimulation delivered.

Test stimulation – The period of time when the clinician and patient explore parameters to determine which are most appropriate to relieve pain.

Therapy – Treatment of a disease or condition.

Warning – A statement describing an action or situation that could harm the patient.

CONTACT INFORMATION

MANUFACTURER

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stim wave TECHNOLOGIES

FREEDOM SPINAL CORD STIMULATOR

TRIAL STIMULATOR AND RECEIVER STIMULATOR

INSTRUCTIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of a physician.

MODEL NUMBERS: FRT4-A001, FRE4-A001

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

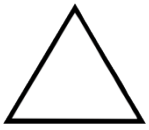
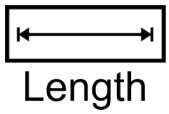
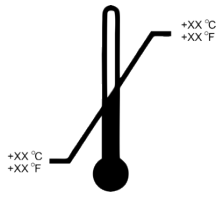
REF	Device reference identification		Consult instructions for use
LOT	Lot number		Do not reuse
QTY	Quantity of product included in package		Do not resterilize
	Use by		Do not use if package is damaged
	Manufacturing date		Store in a cool, dark, dry place
	Manufacturer		Caution
	Stimulator length		Warning
STERILE EO	Sterilization: ethylene-oxide gas		MR Conditional
EC REP	European Authorized Representative		MR Unsafe
	Temperature limits		

TABLE OF CONTENTS

HOW TO USE THIS MANUAL

This manual describes the trial stimulator and permanent stimulator receiver devices, implant procedure accessories, and the methods to optimally implant the device. It also provides important warnings and precautions.

SAFETY INFORMATION

INDICATIONS FOR USE

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

CONTRAINDICATIONS

- **Poor surgical risks –** Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Freedom Stimulator or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the stimulator or WAA and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the stimulator and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:
    - Radio or cell phone transmission stations
    - Facilities using radiofrequency heat sealers or induction heaters

  - Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Freedom SCS System is being affected by EMI then you should:

- Immediately move away from the equipment or object.
- Remove the external transmitting device (the Wearable Antenna Assembly (WAA) from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics

- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS System. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Stimulator fracture – If the Stimulator insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.

When electrocautery is necessary, these precautions must be followed:

- The WAA should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the stimulator.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the stimulator is working as intended.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS System with other active implantable or body worn medical devices. These devices include other neurostimulators, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic resonance imaging (MRI) – An MRI examination may be safely performed under certain specific conditions. Refer to the Product Safety Guide for specific MRI guidelines.

The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, and in the process cause serious harm to the patient or other people or damage to the MR system.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Making sure that the X-ray beam does not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the WAA and turn on stimulation.
- Check for proper stimulation, and that indicator lights are operating as expected.
- Shut off the WAA if it is suspected that the device is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a stimulator. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the stimulator. If RF ablation is used, ensure that ablation is not performed over or near the stimulator.

Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with a limited number of security systems, and have demonstrated that the Freedom SCS System (implanted device and WAA) are not affected by close proximity of the security systems. Any security system may temporarily interrupt spinal cord stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels an increase in stimulation near a security system, they promptly move away from the area and remove the WAA from the body.

When possible, it is best to avoid these security systems or to remove the WAA off while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Induced electrical currents can cause heating that may result in tissue damage.

High-output ultrasonics / lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS System. Use of lithotripsy may result in damage to the device or harm to the patient.

Bone growth stimulators – Safety has not been established for magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the Freedom SCS System. Use of dental drills or ultrasonic probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of the Freedom SCS System. Use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers within the vicinity of the Freedom SCS System. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation at the device. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with the Freedom SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the stimulator site. Magnetic fields will generally not affect the stimulator.

WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

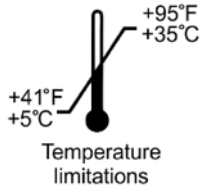
PRECAUTIONS

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal procedures and should review the procedures described in the Instructions for Use.

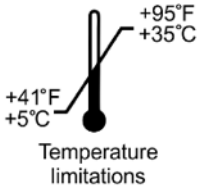
Keep the WAA dry – The WAA is not waterproof. Keep it dry to avoid damage. Do not use the WAA when engaging in water activities.

Storage temperatures – The Freedom SCS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact Stimwave if a storage temperature is surpassed.

Freedom Stimulator
Storage Temperature



Wearable Antenna Assembly
Storage Temperature



Clean the WAA – Clean the outside of the WAA with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the WAA with care – The WAA is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the WAA out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Airline policies - Follow airline policies for use of medical spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

Use the WAA as directed – Use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

Do not dismantle the WAA – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

Use of another patient's WAA - Never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your stimulator to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System. However, take care to not put undue stress on the device. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your amplitude to the lowest setting and turn OFF your System before engaging in activities that could become unsafe. Discuss these activities with your clinician.

ADVERSE EVENT SUMMARY

Implantation of a spinal cord stimulation system is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material.
- Infection.
- Leakage of cerebrospinal fluid.
- Epidural hemorrhage, hematoma, or paralysis.

Therapeutic use of the Freedom SCS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation.
- Stimulator migration, erosion through the skin, or fracture leading to loss of therapeutic effect.
- Electromagnetic interference leading to change in System performance.
- Loss of therapeutic effect despite a functioning system.

Adverse events that could occur with the Freedom SCS System:

- Stimulator migration, resulting in altered stimulation therapy that may be uncomfortable.
- Stimulator fracture, resulting in loss of stimulation.
- Infection, resulting in tissue sensitivity, redness and swelling.

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Patients should be instructed to contact their clinician immediately if they experience any problems. Over time there could be changes in the level of pain control. The patient should contact the clinician if they experience a change in stimulation effectiveness.

PACKAGE CONTENTS

- Tuohy needle – A 14-G needle used to gain access to epidural space.
- Introducer sheath – A 7Fr sheath that is transparent to wireless power is used for insertion of the stimulator into the epidural space.
- Guide wire – A flexible coiled wire used to create a pathway in the epidural space for the stimulator to follow.
- Stimulator – A neurostimulator to be inserted into the epidural space.
- Stylet(s) – Stiff wire(s) inserted into the stimulator body to aid in steering and positioning.
- Sleeve cap – A pellethane cap that creates a seal around the proximal end of the stimulator and acts as an anchoring point to secure the stimulator(s) to connective tissue.

DEVICE SPECIFICATIONS

The Freedom SCS Trial Stimulator is for trial stimulation only. The system can be implanted for no longer than 30 days. Table 1 details the specifications of the Freedom-4 Stimulators. Table 2 lists the component materials and materials in contact with human tissue.

Table 1. Specifications of Freedom-4 Stimulators.

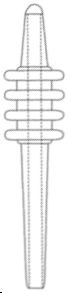
Model number	FRT4 trial version	FRE4 receiver version
		
Stimulator(s):		
Length	45 cm	45 cm
Diameter	1.3 mm	1.3 mm
Electrode(s):		
Number	4	4
Shape	Cylindrical	Cylindrical
Length	3 mm	3 mm
Spacing	4 mm	4 mm
Array Length	24 mm	24 mm
Anchor	Suture through the skin directly to stimulator body, seal with Steri-Strips	Suture Sleeve Cap 
Maximum recommended implant depth	6 cm	6 cm
Implant period	30 Days	Permanent

Table 2. Material in contact with human tissue.

Component	Material	Human tissue contact
Stimulator		
Flexible circuit board	Polyimide	No
Flexible circuit trace	Gold	No
Flexible circuit encapsulation	Parylene C	No
Electrodes	Platinum-Iridium	Yes
Insulation	Polyurethane	Yes
Stimulator tip	Polyurethane	No
Adhesive	Silicone	No
Guide wire	Stainless Steel	Yes
Needle	Stainless Steel	Yes
Introducer sheath	Pebax	Yes
Stylets (curved, straight)		
Handle	Polytetrafluoroethylene (PTFE)	Yes
Wire	Stainless Steel	Yes
Anchor		
Suture Sleeve cap	Pellethane	Yes

INSTRUCTIONS FOR IMPLANTATION (FRT4-A001 AND FRE4-A001)

Implanting clinicians should be experienced in procedures that gain access to the epidural space and familiar with the product labeling.

PREPARING FOR SURGERY

Before opening the stimulator package, verify the package integrity, model number, and use-by date. This product is provided sterile. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Stimwave for any questions regarding packaging and expiration dates.

⚠ CAUTION:

To reduce the risk of stimulator damage that might result in intermittent or lost stimulation:

- Use only the needle and introducer sheath supplied in the kit.
- Use a shallow needle-insertion angle (45 degrees or less) when inserting or withdrawing the needle into or out of the epidural space.
- Do not bend, kink, or stretch the stimulator or stylet.
- Do not use any instrument to handle the stimulator.
- Use care when replacing a stylet.
- Avoid excessive pressure on the stimulator.

DEVICE PLACEMENT

1. If necessary, make an incision at the needle-entry site to the subcutaneous fascia.
2. Use a paramedian approach lateral to the midline to insert the needle assembly into the epidural space at a shallow angle until you encounter resistance from the ligamentum flavum (see Figure 1). Use fluoroscopy to visualize the location of the needle assembly.
   NOTE: *Use ONLY the needle and introducer provided in the kit. Do not remove the introducer from the needle when driving the needle into the epidural space.*

⚠ WARNING:

As with any spinal procedure, the risk of serious injury to the patient (e.g., hemorrhage, hematoma, or paralysis) increases as the needle insertion site moves up from a lumbar location (lowest risk) to a cervical location (highest risk). Select a vertebrae location for needle insertion that provides the widest possible access to the epidural space.

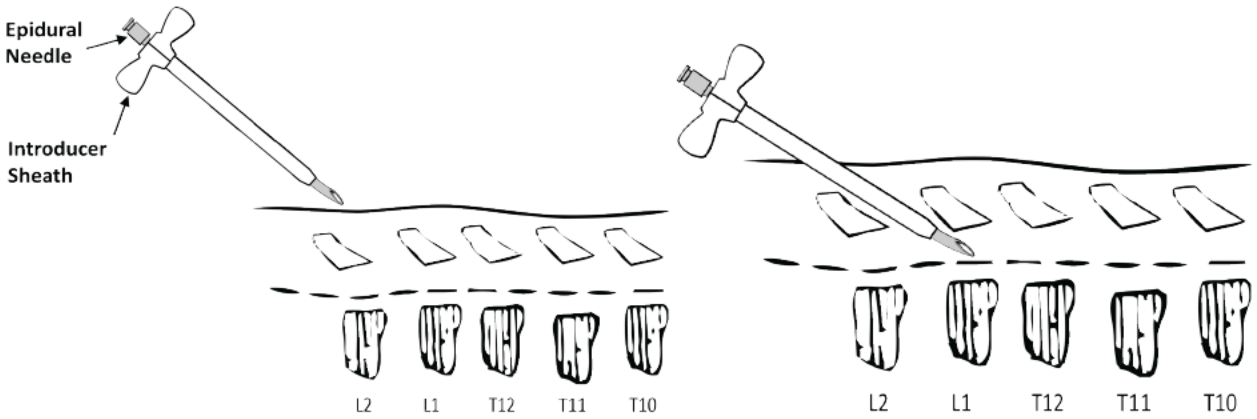


Figure 1. Insert the introducer sheath and needle assembly into the epidural space.

3. Under fluoroscopy verify that the introducer and needle location are in the correct position (Figure 1).
4. Rotate the needle assembly so that the beveled edge faces cephalad and remove the needle stylet.
5. Confirm entry into the epidural space using the loss-of-resistance technique with air or sterile water.
6. If a second device is indicated, repeat steps 1 – 5 noting these recommendations:
   - Implant the second device parallel to the first stimulator and approximately 1 – 3 mm lateral to the physiological midline.
   - Introduce the second device one vertebral space below the first device entry location. This will help prevent nicking or cutting the first device and to allow sufficient space for suturing both devices and anchors.
   - Stagger the contacts or place them several vertebral spaces apart, depending on the position that produces the most effective paresthesia.

> ⚠ CAUTION:
>
> Do not use contrast media. Contrast media might obscure the field of vision.

7. Insert the guide wire through the needle; advance no farther than 1-3 cm past the needle tip.
   NOTE: *Keep the guide wire track on the intended pathway (otherwise steering and manipulating will be more difficult).*
8. Remove the needle while maintaining the position of the introducer (Figure 2).

NOTE: *The metal Tuohy needle* ***blocks*** *the energy from the WAA. The needle must be removed before intraoperative stimulation. The introducer is RF transparent and can be used throughout intraoperative testing.*

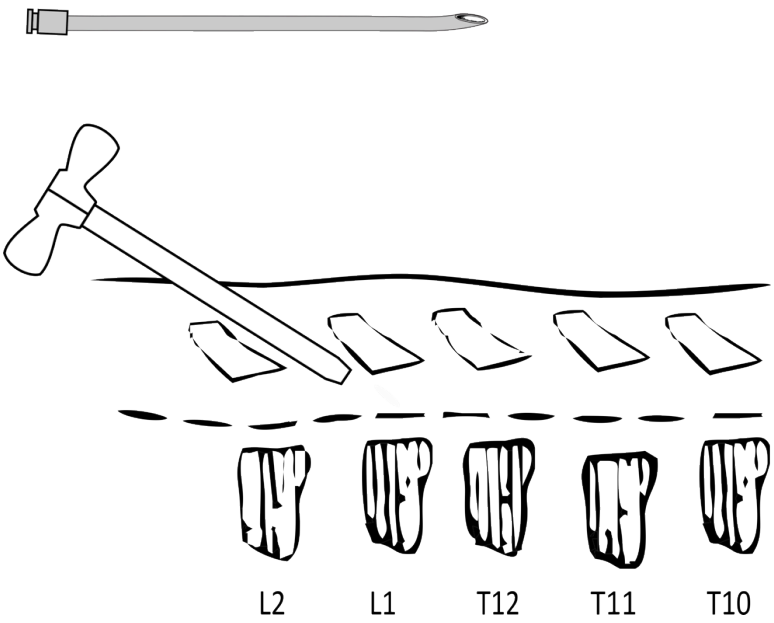


Figure 2. Introducer remains in epidural space while the needle is removed.

9. Slowly insert the device through the introducer and advance to the location that has the highest probability of meeting paresthesia coverage (see Figure 3). Use fluoroscopy to visualize the location.

   NOTE: *If resistance is encountered during device advancement with the bent stylet, exchange for the straight stylet and use short, firm movements to advance the device.*

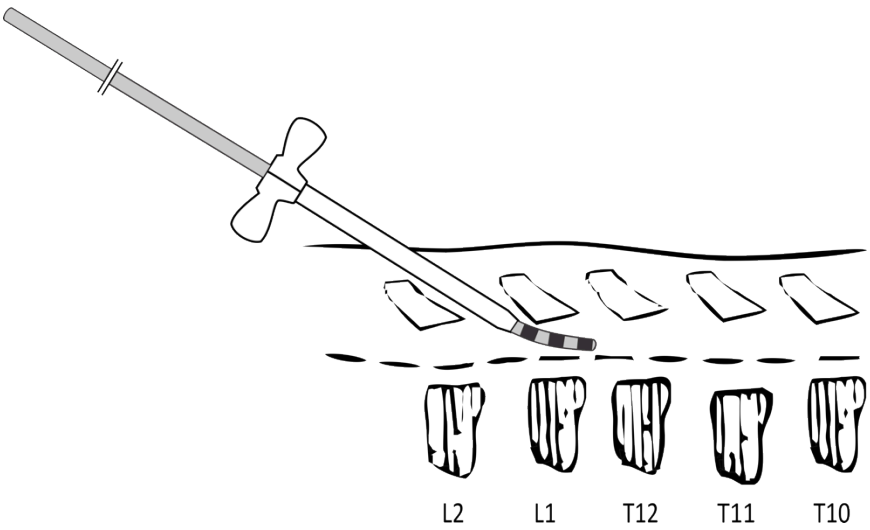


Figure 3. Pass the stimulator through the interior lumen of the introducer sheath.

10. After verifying the device position under fluoroscopy (anterior-posterior and lateral views), compare that location with the location that has the highest probability of therapeutic paresthesia coverage.
    NOTE: *To reduce the possibility of migration, insert enough length to extend at least three vertebral bodies into the epidural space.*

TESTING STIMULATION INTRAOPERATIVELY

NOTE: *This procedure requires a Wearable Antenna Assembly, which is packaged in a separate kit.*

1. While holding the stimulator in place completely withdraw the stylet.
2. Place the WAA in a sterile drape or sterile fluoroscope bag over the region directly above the most proximal implanted electrode (see Figure 4).

> ⚠ CAUTION:
>
> To prevent possible unexpected stimulation (jolting or shocking sensations):
>
> - Program parameter changes in small increments above the perception threshold.
> - Decrease the amplitude before:
>   - Changing electrode polarities.
>   - Placing the WAA over the patient's back.
>   - Turning ON the neurostimulator.

3. Identify the most appropriate stimulation parameters, beginning at a medium pulse width and frequency range. Increase the amplitude while asking the patient close-ended questions to identify the perception threshold, the discomfort threshold, and the area of paresthesia coverage.
   NOTE: *If good paresthesia coverage of the painful area is not obtained, change the electrode settings before repositioning the device.*
4. When implanting a second device, ensure that the electrodes are spaced no more than 4 cm lateral or 4 cm superior of one another. Placement of stimulators at a distance larger than as described will result in poor performance. Refer to Figure 5 for an illustration.
5. If implanting two devices, repeat steps 2 – 3 for the second device; optimize paresthesia coverage using both devices.
6. In the patient's chart, document the stimulator position that provided appropriate stimulation coverage. Record the stimulation settings and patient responses. Include a fluoroscopic image of the final stimulator position.

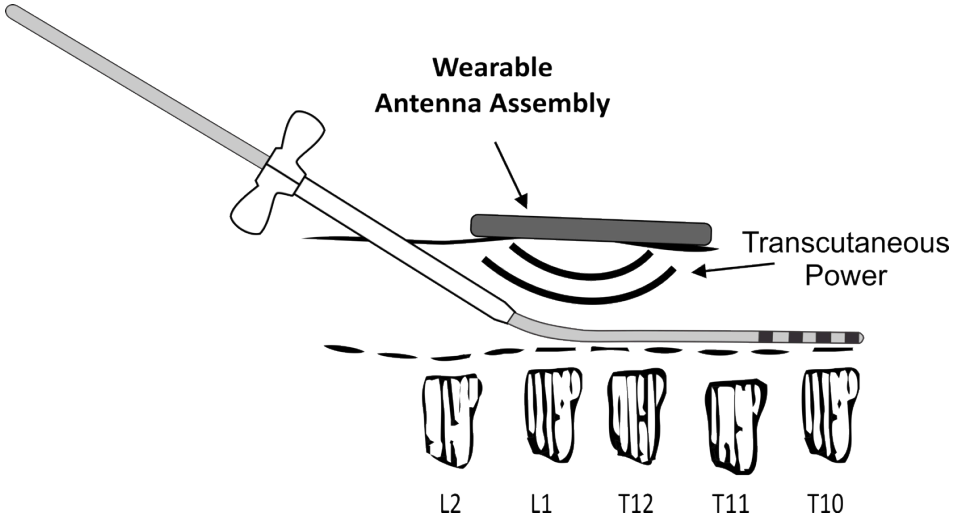


Figure 4. Intraoperative stimulation using the WAA.

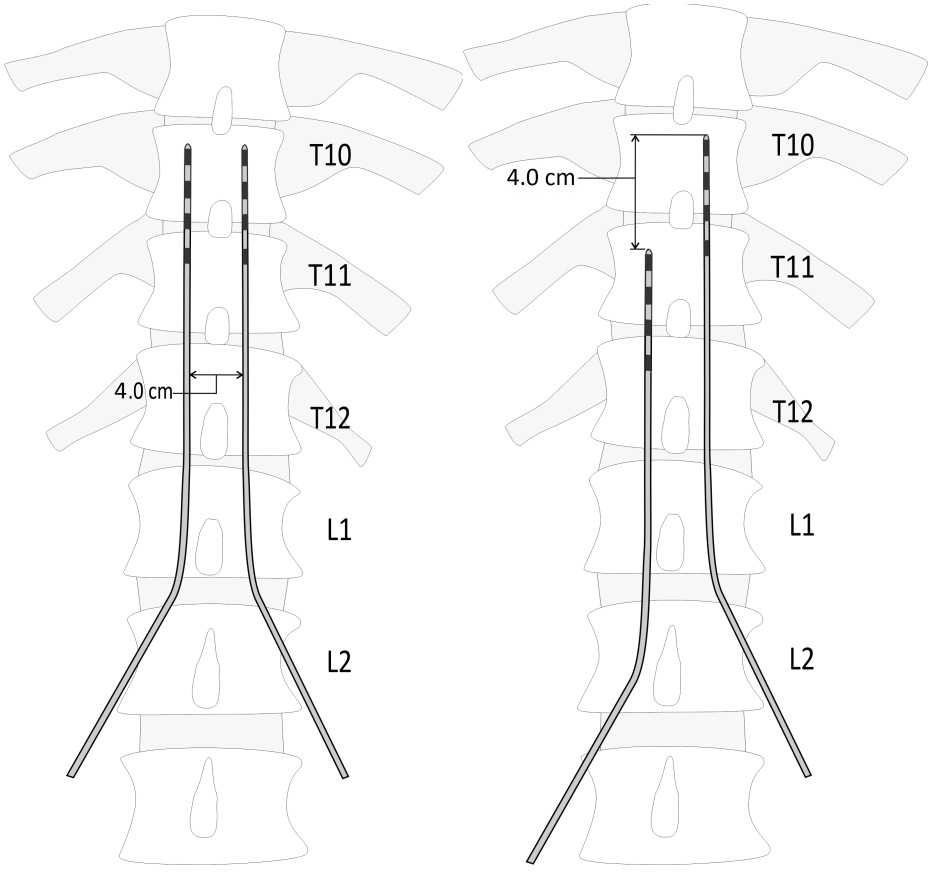


Figure 5. An illustration of two devices separated by no more than 4.0 cm.

ANCHORING THE TRIAL STIMULATOR (FRT4-A001 ONLY)

1. While maintaining the stimulator position by placing light pressure on the proximal end, use minimal force to remove the introducer (See figure 6).

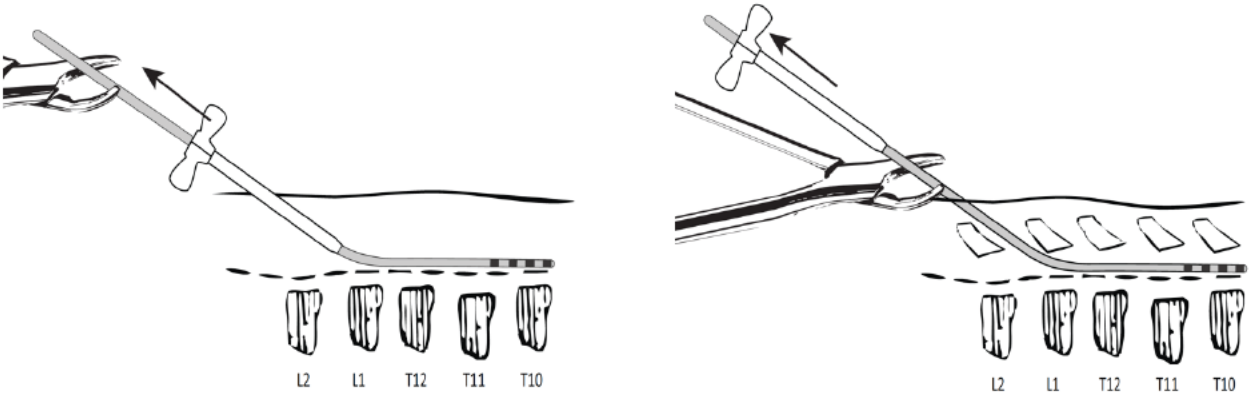


Figure 6. Hold the device using flat, dull tweezers or forceps while removing the introducer.

> ⚠ CAUTION:
>
> Use minimal traction to remove the introducer as sudden jarring could dislodge the device.

2. Tie '2-0 nonabsorbable suture (silk or some other braided polyester mesh) around the device body.
3. Tie the device to tissue using the suture.
4. Use sterile scissors to cut the excess stimulator body length away from the implanted portion.
5. Close the incision using sterile skin closures and dressings.

ANCHORING THE RECEIVER STIMULATOR (FRE4-A001 ONLY)

1. Prepare the anchor site by making a longitudinal incision around the introducer shaft. Dissect down to the supraspinous ligament and establish hemostasis. Refer to Figure 7.

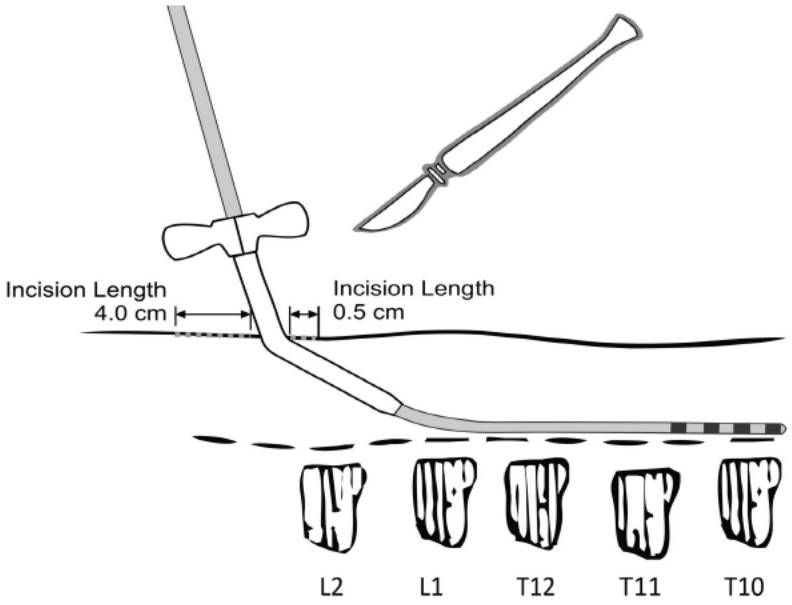


Figure 7. Make a longitudinal incision around the introducer sheath shaft.

> ⚠ CAUTION:
>
> Use care to avoid cutting into the introducer or device. Point the blade in a direction away from the introducer.

2. While maintaining the position of the device by placing light pressure on the proximal end, use minimal force to remove the introducer.

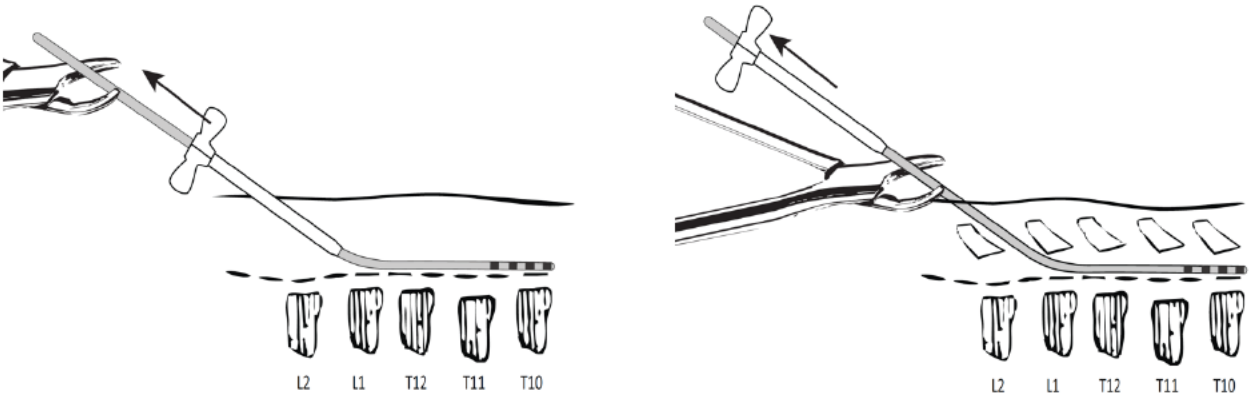


Figure 8. Hold the device using flat, dull tweezers or forceps while removing the introducer.

> **CAUTION:**
>
> Use minimal traction to remove the introducer as sudden removal might dislodge the stimulator.

3. Use sterile scissors to cut the excess stimulator body length away from the implanted portion. Maintain at least 5 cm of stimulator body to allow for proper suture sleeve cap attachment (see Figure 9).

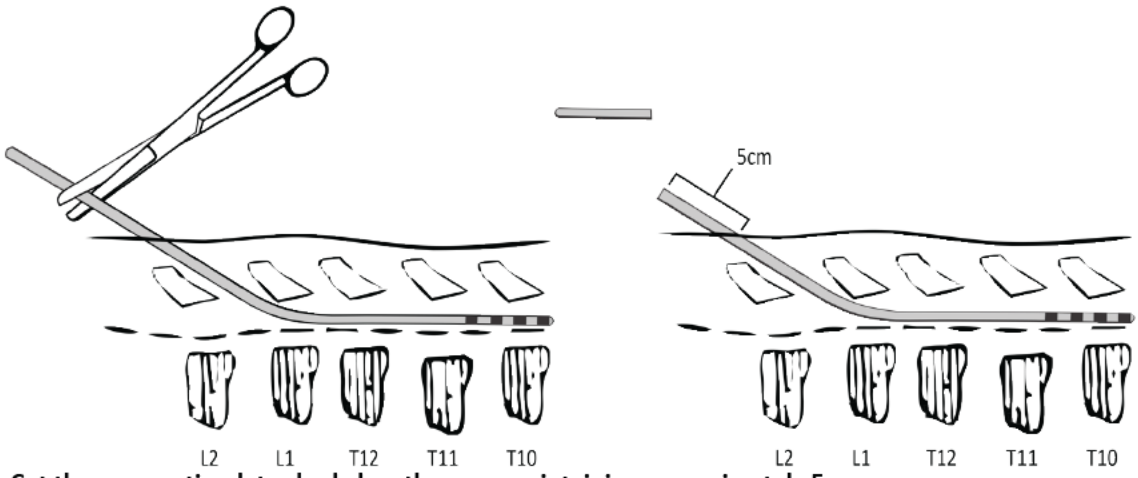


Figure 9. Cut the excess stimulator body length away, maintaining approximately 5 cm.

4. Slide the suture sleeve cap onto the proximal end of the device and continue sliding until it reaches the final position (see Figure 10). Use care to maintain the device position.

CAUTION:

- Do not force the sleeve cap past the final position, this could damage the device.
- Hold the stimulator using flat, dull tweezers or forceps while removing the suture sleeve cap to reduce the likelihood of stimulator displacement.

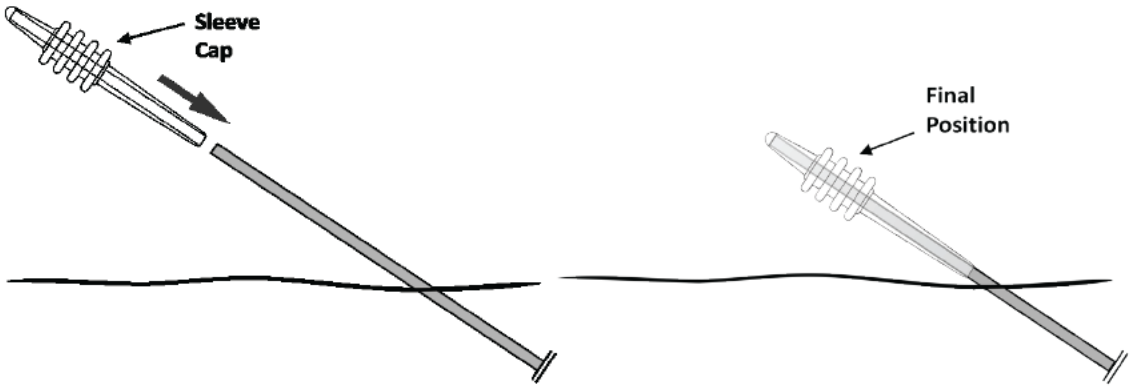


Figure 10. Slide the sleeve cap onto the proximal end of the device.

5. Secure the device within the sleeve cap using 2-0 non-absorbable sutures.
6. Use 2-0 non-absorbable sutures to secure the sleeve sleeve cap to the connective tissue (see Figure 11).

   NOTE: *For larger patients where the sleeve cap cannot be sutured directly to connective tissue, sutures may be applied directly to the stimulator body with no risk of damaging the stimulator electronics.*

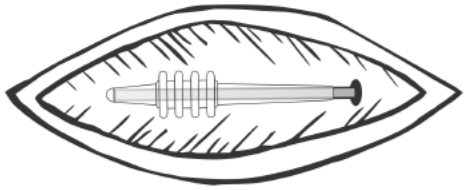


Figure 11. The sleeve cap in the final position and ready for sutures.

7. Ensure that the stimulator has not moved by performing intraoperative stimulation to verify test stimulation parameters. If the stimulator has moved, reposition it.
8. Close the incision using sterile skin closures and dressings.

DEVICE EXPLANT PROCEDURE

1. Identify the incision site from the original implantation procedure. Use fluoroscopy to visualize the location.
2. Make an incision to the depth of the proximal end of the stimulator (referred to as the "tail").
3. If applicable, cut sutures free of any tissue structures or scarring.
4. Remove the device by slowly pulling on the proximal end.
5. After the device has been removed, verify that all components are intact and that all implanted materials are accounted for.
6. Close the incision using standard surgical techniques and dressings.

DEVICE DISPOSAL

Explanted devices are not to be re-sterilized or re-implanted. Dispose of the used Freedom Stimulator according to local laws and regulations.

MRI SAFETY INFORMATION

Magnetic resonance imaging (MRI) may be safely performed under certain conditions on a patient with a single Freedom Stimulator. In-vitro testing demonstrated that the Freedom Stimulator is MR Conditional. All other components of the Freedom SCS System are MR Unsafe, and must not be allowed in the MR system room (i.e., these components must be removed from the patient or are not allowed in the MR system room). Freedom System components are labeled as follows:

 MR Conditional Component	 MR Unsafe Components
• Freedom-4 Stimulator (Receiver Only). A patient with the Freedom-4 Stimulator may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. See specific conditions for safe scanning given below.	• Freedom-4 Stimulator (Trial Stimulator) • Wearable Antenna Assembly • Programmer • Wireless Charging Pad • Needles • Guidewire • Stylets

The WAA **MUST NOT** be present in the MR system room at **ANY TIME**. Failure to adhere to the specific requirements described in this manual can result in tissue damage, severe injury, or death. Please use the contact information found on the last page of this manual for additional information.

DO NOT have an MRI examination while the trial stimulator is implanted. The trial stimulator is MR Unsafe. Only the receiver stimulator for chronic use is MR Conditional.

Follow these instructions when preparing for an MRI examination:

- Bring your current patient ID card to every MRI appointment.
- Show the MRI personnel your patient ID card. This indicates that the manufacturer of your System is Stimwave Technologies. The ID card also identifies your System model number.

The MRI personnel can use this information to obtain instructions to determine the eligibility of your System for the MRI procedure. Safe MR conditions can then be used.

⚠ WARNING:

Remove the Wearable Antenna Assembly from the patient before entering the MR system room. The strong magnetic field of the MR system could attract or otherwise damage the unit and in the process cause serious harm or damage to the MR system.

PREPARATION FOR AN MRI

The following steps must be performed prior to an MRI on a patient with an implanted Freedom Stimulator.

1. Allow at least six weeks from the date of implantation to the time of the MRI.
2. Remove the WAA (the external component of the Freedom System) from the patient before allowing the patient to enter the room where the MRI procedure will take place.
3. Do not conduct an MRI procedure if the patient has any other implant or health condition that prohibits or contraindicates an MRI examination.
4. Instruct the patient to immediately inform the MRI system operator (i.e., the MRI technologist) if any discomfort, stimulation, shocking, or heating occurs during the examination.
5. The patient must be conscious during the MRI in order to be able to inform the MRI operator of any problems.
6. Verify with the MRI operator that all proposed MRI conditions comply with the requirements specified in this manual. If any MRI parameter is not met and cannot be modified, do not perform the MRI procedure.

MRI CONDITIONS MR

NOTE: *This information applies only to cases where a single Freedom Stimulator is implanted.*

The MRI scan sequences must meet the following conditions. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer. If the MRI scan sequences do not meet the conditions, then the pulse parameters must be adjusted so that they comply.

Non-clinical testing has demonstrated the Freedom Stimulator is MR Conditional. The Freedom Stimulator can be scanned safely under the following conditions.

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Maximum spatial gradient field of 30 T/m (3,000 Gauss/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of continuous scanning.
- No restrictions on position of the Freedom Stimulator with respect to MR system bore or body part undergoing MR imaging.
- No other components of Freedom SCS System (e.g. WAA, wireless charging pad, needle, stylets, guidewire) may be taken into the MR system room.
- No restrictions on use of transmit RF coils.

NOTE: *Enter the patient's weight into the MR system console to ensure that the whole body averaged specific absorption rate (SAR) is estimated correctly.*

Under the scan conditions defined above, the Freedom Stimulator is expected to produce a maximum temperature rise of 2.3ºC in a 1.5-Tesla/64-MHz system or 1.9ºC in a 3-Tesla/128-MHz system after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact extends approximately 15 mm from the device when imaged with a gradient echo pulse sequence and a 3 Tesla/128-MHz MRI system.

DURING AN MRI EXAMINATION

The patient should be conscious during the MRI procedure. Monitor the patient both visually and audibly. Check the patient between each MR imaging sequence. Discontinue the MRI examination *immediately* if the patient is unable to respond to questions or reports any problem.

POST-MRI REVIEW

Verify that the patient feels normal. Verify that the Freedom Stimulator is functional by checking its response to the WAA.

CONTACT INFORMATION

MANUFACTURER

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Internet: www.stimwave.com

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Australia

stim wave TECHNOLOGIES

FREEDOM SPINAL CORD STIMULATION SYSTEM

MALIBU PROGRAMMER USER MANUAL

Caution: Federal law restricts this device to sale by or on the order of a physician.

MALIBU PROGRAMMING SOFTWARE VERSION 1.0

TABLE OF CONTENTS

HOW TO USE THIS MANUAL

This user manual shall be used to program the Wearable Antenna Assembly (WAA) Malibu Software. The Malibu Software connects via Bluetooth® to the WAA. Only a trained clinical representative may use the Malibu Software. This manual also provides the warnings and precautions for the Freedom Spinal Cord Stimulator (SCS) System. Refer to the Freedom Product Safety Guide to learn about EMC related safety information.

SAFETY INFORMATION

INDICATIONS FOR USE

The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The FRT4-A001 device is for trial stimulation of the FRE4-A001 device for permanent implantation.

CONTRAINDICATIONS

- **Poor surgical risks –** Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Freedom Stimulator or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the lead or WAA and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Users who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the Freedom SCS System. The energy in high-level areas can be transferred through the lead and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:

  - Radio or cell phone transmission stations
  - Facilities using radiofrequency heat sealers or induction heaters
  - Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the Freedom SCS System may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately.

WARNINGS

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System.
However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

If you suspect that your Freedom SCS System is being affected by EMI then you should:

- Immediately move away from the equipment or object.
- Remove the external transmitting device (the Wearable Antenna Assembly (WAA) from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation.
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics.

- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics.
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area).
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment.
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals.

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom SCS System. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Lead fracture – If the lead insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.

When electrocautery is necessary, these precautions must be followed:

- The WAA should be taken off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the lead.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm that the lead is working as intended.

Active Implantable or Body Worn Medical Devices – Safety has not been established for patients who use the Freedom SCS System with other active implantable or body worn medical devices. These devices include other neurostimulators, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

Magnetic resonance imaging (MRI) – An MRI examination may be safely performed under certain specific conditions. Refer to the Product Safety Guide for specific MRI guidelines.

The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, and in the process cause serious harm to the patient or other people or damage to the MR system.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a Freedom Stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Making sure that the X-ray beam does not dwell over the device for more than a few seconds.

After CT scanning directly over the implanted device:

- Place the WAA and turn on stimulation.
- Check for proper stimulation, and that indicator lights are operating as expected.
- Shut off the WAA if it is suspected that the device is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a stimulator. RF ablation may cause induced electrical currents that result in heating and tissue damage. Do not use RF ablation anywhere near the stimulator. If RF ablation is used, ensure that ablation is not performed over or near the stimulator.

Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with a limited number of security systems, and have demonstrated that the Freedom SCS System (implanted device and WAA) are not affected by close proximity of the security systems. Any security system may temporarily interrupt spinal cord stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels an increase in stimulation near a security system, they promptly move away from the area and remove the WAA from the body.

When possible, it is best to avoid these security systems or to remove the WAA off while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Induced electrical currents can cause heating that may result in tissue damage.

High-output ultrasonics / lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS System. Use of lithotripsy may result in damage to the device or harm to the patient.

Bone growth stimulators – Safety has not been established for magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

Dental drills and ultrasonic probes – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the Freedom SCS System. Use of dental drills or ultrasonic probes may result in damage to the device or harm to the patient.

Electrolysis – Safety has not been established for electrolysis within the vicinity of the Freedom SCS System. Use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers within the vicinity of the Freedom SCS System. Use of lasers may result in damage to the device or harm to the patient.

Radiation therapy – Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with the Freedom SCS System. Use of radiation therapy could cause damage to the device or harm to the patient.

Transcutaneous electrical nerve stimulation – Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with the Freedom SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the stimulator site. Magnetic fields will generally not affect the stimulator.

WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

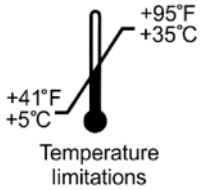
PRECAUTIONS

Physician training – Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal procedures and should review the procedures described in the Instructions for Use.

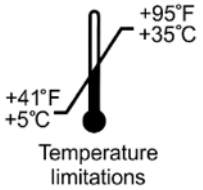
Keep the WAA dry – The WAA is not waterproof. Keep it dry to avoid damage. Do not use the WAA when engaging in water activities.

Storage temperatures – The Freedom SCS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact Stimwave if a storage temperature is surpassed.

Freedom Lead
Storage Temperature



Wearable Antenna Assembly
Storage Temperature



Clean the WAA – Clean the outside of the WAA with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

Handle the WAA with care – The WAA is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the WAA out of the reach of children and pets.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause damage to the patient or to the System.

Physician instructions – Always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Airline policies - Follow airline policies for use of medical spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

Use the WAA as directed – Use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

Do not dismantle the WAA – Do not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, contact the clinician for help.

Flammable or Explosive Environments – Do not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

Use of another patient's WAA - Never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

Activities requiring excessive twisting or stretching – Avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause your lead to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Scuba diving or hyperbaric chambers – Do not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with the clinician.

Skydiving, skiing, or hiking in the mountains – High altitude should not affect the System. However, take care to not put undue stress on the device. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the device. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. You should reduce your amplitude to the lowest setting and turn OFF your System before engaging in activities that could become unsafe. Discuss these activities with your clinician.

ADVERSE EVENT SUMMARY

Implantation of a spinal cord stimulation system is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material
- Infection
- Leakage of cerebrospinal fluid
- Epidural hemorrhage, hematoma, or paralysis

Therapeutic use of the Freedom SCS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation
- Lead migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning system

Adverse events that could occur with the Freedom SCS System:

- Lead migration, resulting in altered stimulation therapy that may be uncomfortable
- Lead fracture, resulting in loss of stimulation
- Infection, resulting in tissue sensitivity, redness and swelling

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Contact your clinician immediately if you experience any problems. Over time there could be changes in the level of pain control. Contact your clinician if you experience a change in stimulation that you believe is a result of the lead slipping from the implant site.

SOFTWARE INFORMATION

The Malibu programming software runs on Apple iPad, iPad 2, iPad (3rd and 4th generation), iPad Air, and iPad Mini. The software is not available through main Apple App Store. The software is distributed directly through Stimwave.

MALIBU PROGRAMMING APPLICATION DESCRIPTION

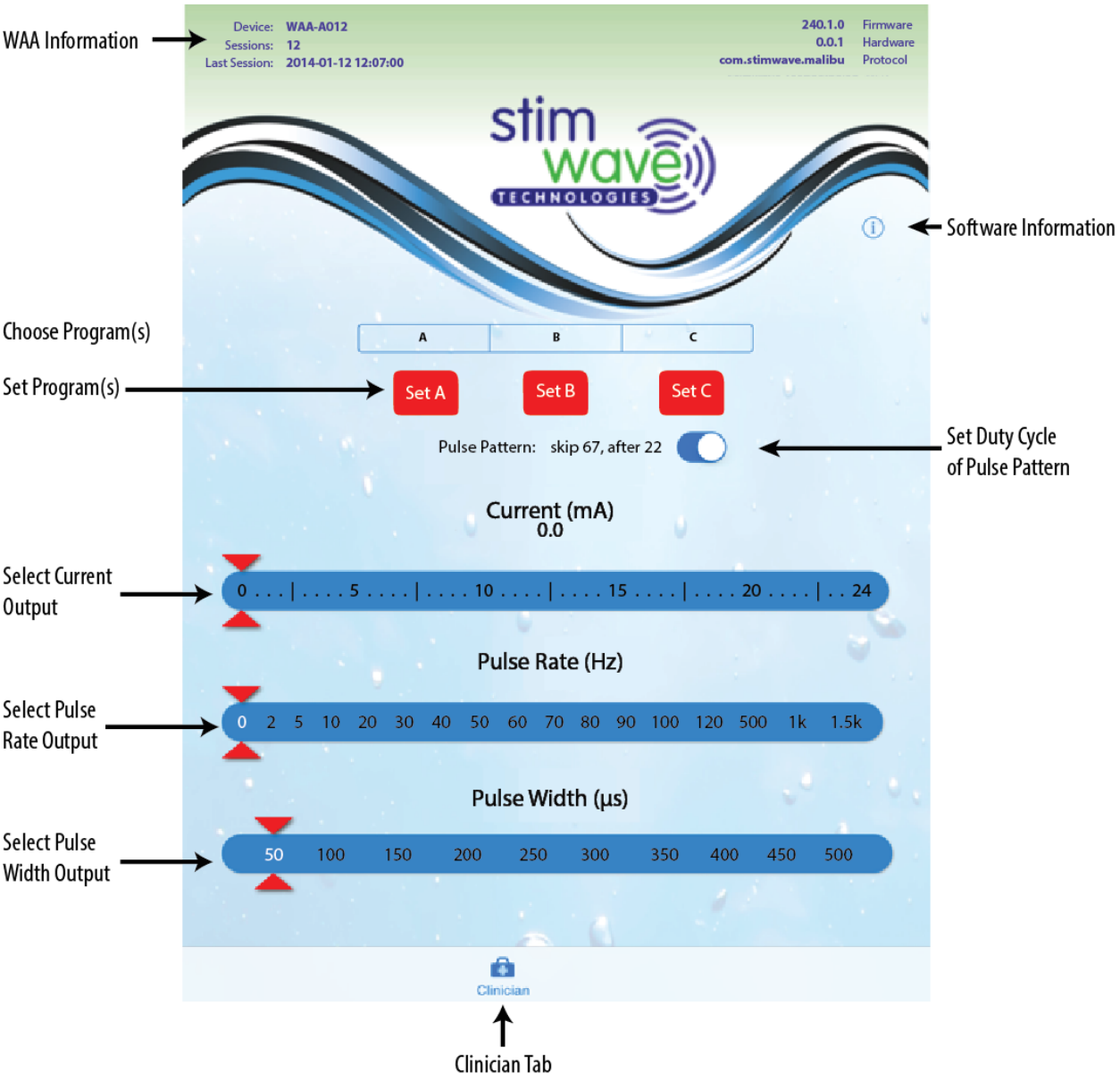


Figure 1: A screenshot of the programming application with buttons and sliders identified.

PROGRAMMING STIMULATION PARAMETERS

Each WAA can be communicated with by Bluetooth® connection. An iPad pre-loaded with the Malibu Programming App is required. Once connected, the clinician can program the WAA.

The patient may choose from three pre-programmed parameter-setting combinations. Each combination will have a set RATE and WIDTH provided by the clinician. The patient can change programs by pressing the A, B, or C buttons on the WAA.

Notes:

- *Stimulation gain will always default to zero when selecting a new program. This holds true whether the program is selected on the WAA or the Malibu Programming App.*
- *Always notify the patient when stimulation is about to begin.*

CONNECTING TO THE WEARABLE ANTENNA ASSEMBLY

The iPad communicates with the WAA via an encrypted Bluetooth® connection. This is accomplished by first pairing the WAA with the iPad via the native iPad application. The WAA will not be automatically "discoverable" by Bluetooth® devices, and must be made discoverable. To enable Bluetooth mode on the WAA:

1. Ensure that the WAA is powered "OFF".
2. While pressing and holding down the "+" button, press the "POWER" button.

To pair the WAA with the iPad:

1. Power on the iPad and ensure that the WAA is powered "ON" (NOTE: you must first make the WAA discoverable before it can be paired).
2. Select "Settings" from the iPad. (Figure 2a)
3. Select "Bluetooth" from the list of Settings. (Figure 2b)
4. Confirm that Bluetooth® is turned on.
5. Wait for the iPad to identify Bluetooth® devices within range. Select the WAA unique identification number from the list of available devices. (Figure 2b)
6. Connection is made and secure when the iPad identifies the device as "Paired".

NOTE: If difficulty is experienced during the pairing process:

A. Ensure that all other Bluetooth® or WiFi devices in the room are turned off.
B. Try moving closer to the WAA, or further away from other devices.
C. Repeat steps for making the WAA "discoverable" by Bluetooth® devices.

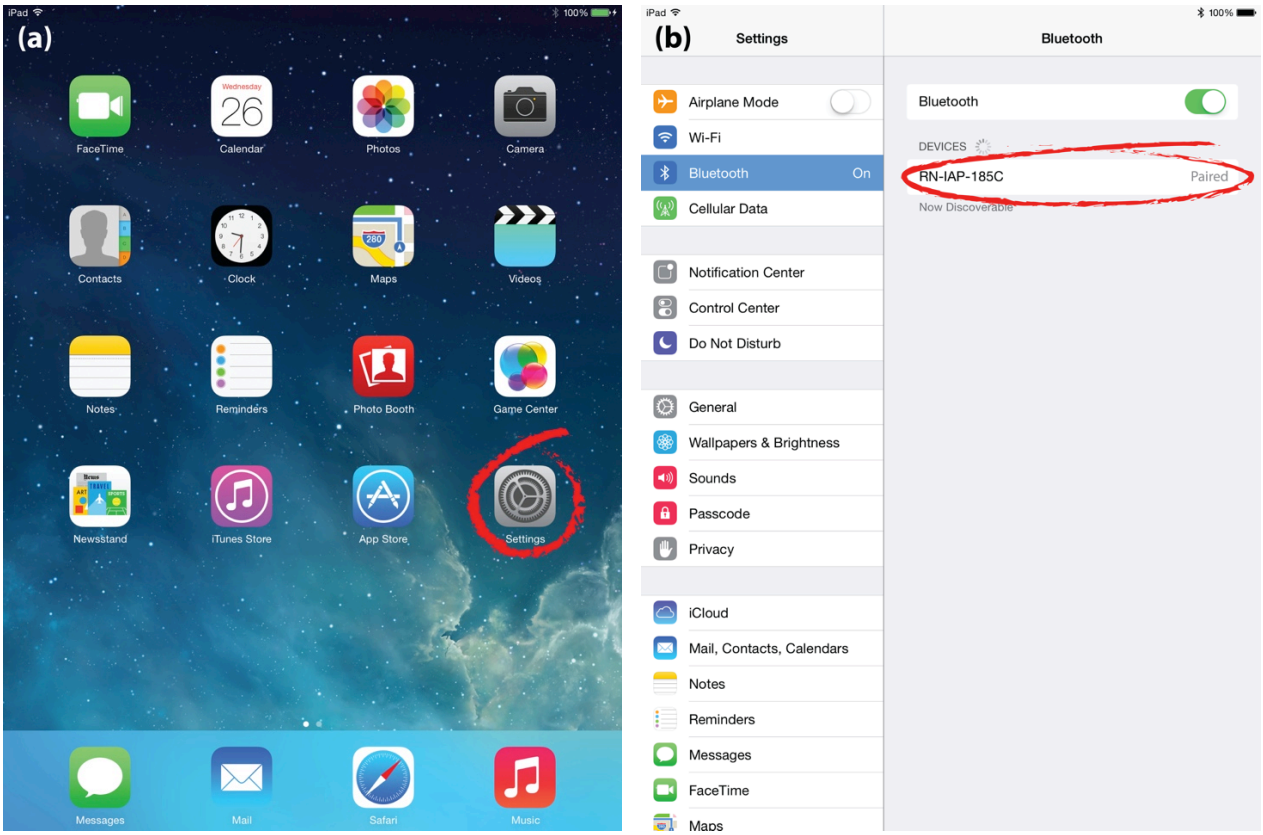


Figure 2: (a) A screenshot of selecting iOS settings, and (b) Pairing of the iPad with the WAA via Bluetooth®

You are now ready to open the Malibu Programming Application.

OPENING THE MALIBU PROGRAMMING APPLICATION

The Malibu Programming Application must be running in order to program stimulation settings. The iPad will request a connection password before programming stimulation settings and transmits data. The password is specific to the WAA and provided on the back of the WAA. The application will not open completely until the correct password is entered into the Malibu Programming Application.

1. Ensure that the WAA is paired to the iPad before continuing. (NOTE: The Application can be opened without pairing a WAA, but stimulation settings cannot be programmed until a WAA has been paired.)
2. Navigate through the iPad screens to find the Malibu Programming Application icon.
3. Select the icon to open the Malibu Programming Application.
4. Once open, the Application will ask the user to select an Accessory. (Figure 3a) This should be the same WAA unique identification number.
5. When prompted, enter the Patient ID, the connection password (Device ID) for the specific WAA, and the WAA Model Number. (Figure 3b) (NOTE: The connection

password is the lot number of the WAA stamped on the back of the unit and printed on the WAA Packaging Label.)

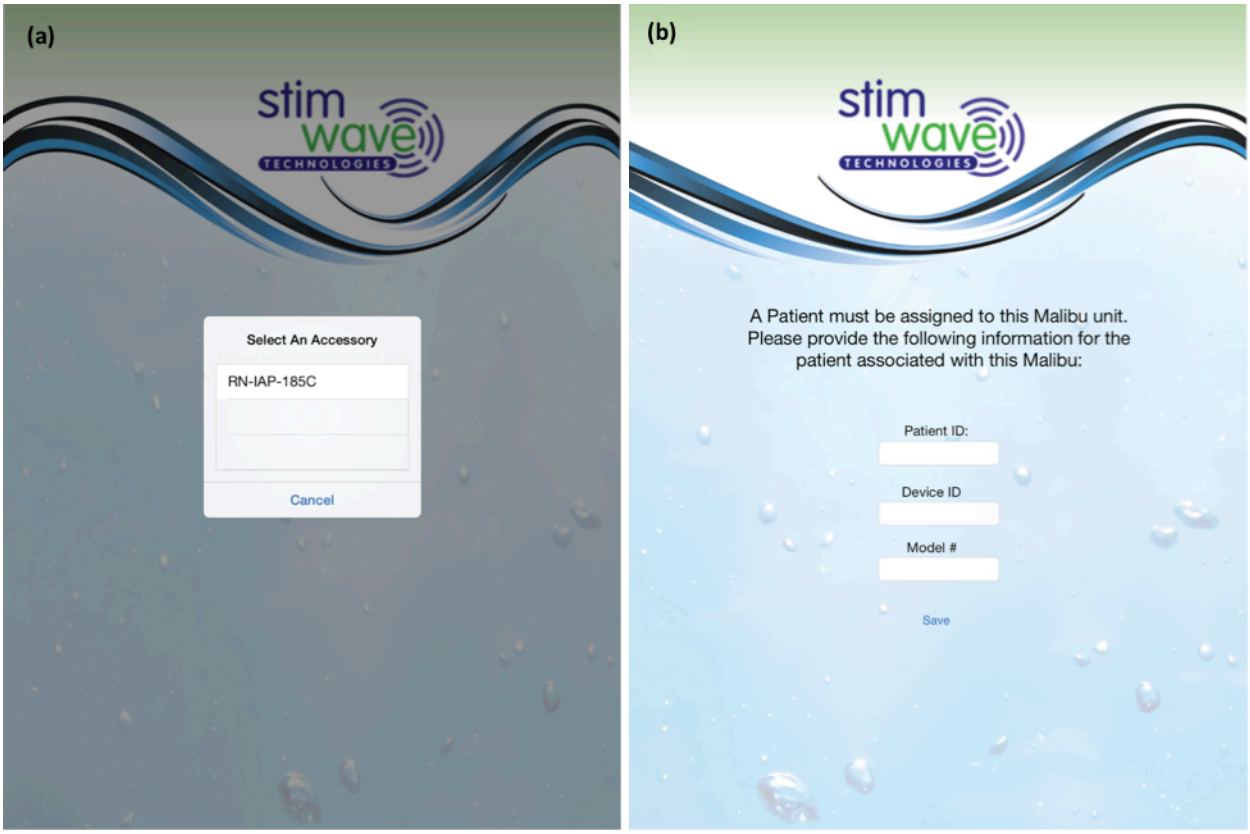


Figure 3: (a) selecting a(n) WAA/accessory, and (b) entering in WAA connection password.

You are now ready to communicate with the WAA.

SELECTING A PROGRAM

Program stimulation parameters can be selected by the corresponding program button. To select a program:

1. Select the Clinician Tab at the bottom of the iPad screen.
2. Press the "A" button in the Malibu Programming Application.
3. The program "A" settings are displayed.

SETTING STIMULATION PARAMETERS

The Malibu Programming Application will open in the clinician tab. This screen describes the current stimulation parameters. Stimulation parameters can be modified and the programs can be set here. There are no electrode polarity options in this version of the Malibu Programming Application. To change the stimulation parameters:

1. While in the Clinician Tab, Identify the slider that corresponds to the desired stimulation parameter.
2. Use your finger to move the slider carriage(s) to the new parameter(s).
3. Press the “Set A” button to send the new parameters to the WAA.
4. The WAA program “A” has now been set.

Once the stimulation parameters have been set, turn off the WAA to disable Bluetooth® discoverability. After 15 minutes of inactivity of Bluetooth communication, the WAA will automatically disable Bluetooth®.

TROUBLESHOOTING

This information can help you solve problems that may arise with the Malibu Programming App. If a problem is not solved after several attempts, or if a problem is not described here, review the connecting device's user manual or contact Stimwave.

Problem	Possible Solution
• Application is not connecting to the WAA	• Turn WAA off and follow the steps on page 13 to make Bluetooth® discoverable • Check to ensure that the WAA is turned on • Turn off other Bluetooth or wireless devices in the room • Move closer to the WAA or farther away from other wireless devices
• Application is not changing the stimulation parameters • The programs are not retaining the stimulation parameters set	• Check that a Bluetooth® connection has been made • Confirm the serial number of the WAA matches that which is displayed by the Application • Power cycle the WAA • Power cycle the Application
• Application is operating erratically	• Ensure no nearby equipment is generating EMI. EMI may interfere with device function

WIRELESS INFORMATION

The Freedom SCS System uses wireless technology to program the WAA and to power the stimulator. The WAA is programmed utilizing a Bluetooth® data communication protocol. Bluetooth® is used only during programming sessions and only by a trained clinician. Programs are stored on the WAA, which can then be used on a daily basis The WAA communicates with the stimulator using a pulsed radio frequency signal centered at a frequency of 915 MHz.

Wireless Specifications	
Transmission Frequency of WAA	915 megahertz (MHz)
Bandwidth of WAA	149 kilohertz (kHz)
Power Output of WAA	15 watts (W) peak or 1.1 watt (W) average power: Pulse-Amplitude Modulation (PAM) and Pulse-Width Modulation (PWM)
WAA tissue penetration depth	Up to 4 inches or 10 cm
Quality of Service	In order for the Freedom SCS System to operate, the WAA must be in close range of the Stimulator. The WAA should be centered over the Stimulator within 0.8 inches or 2 cm. To better ensure proper function, the WAA should be worn in the same position as when it was originally fitted. When the wireless link between the WAA and Stimulator is broken, stimulation will cease. The wireless link may not function in the presence of large magnetic or radio fields.
Frequency of Bluetooth®	2.4 gigahertz (GHz)
Bandwidth of Bluetooth®	900 kHz
Power of Bluetooth®	2.5 miliwatts (mW)
Bluetooth® Operating Distance	4 to 5 meters
Wireless Link Performance	Wireless link active less than 10% of the time when the WAA is approximately 1 inch or closer to the implant.
Wireless Security	The Stimulator will only operate if it is within a very short distance of the WAA and such communication is disabled when Bluetooth® is enabled. The WAA uses encryption and proprietary data protocols to reduce the likelihood of inadvertent control or malicious "hacking" of the System through Bluetooth®. Only the iPad Malibu Application is able to communicate with the WAA via Bluetooth®. No identifiable personal data is stored or transmitted by the WAA.
Bluetooth Quality of Service	Typical Bitrate: 360 bps Maximum Data Latency: 100ms Maximum Operating Distance: 4 to 5 meters

CONTACT INFORMATION

- MANUFACTURER

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