

Stimwave Technologies Incorporated Traditional 510(k) Premarket Submission Freedom Spinal Cord Stimulator (SCS) System

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 K141399

FDA CDRH DMC

Dear Sir or Madam:

MAY 2 8 2014

Received

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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Stimwave Technologies Incorporated Traditional 510(k) Premarket Submission Freedom Spinal Cord Stimulator (SCS) System

882.5880 **Regulation Number:** 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 None; this is the only device in the submission Multiple Devices: 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 Outstion

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?		Х
Is the device provided sterile?	Х	
Is the device intended for single use?	Χ	
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?		Х
Does the device contain a biologic?		X
Does the device use software?	Х	
Does the submission include clinical information?	Х	
Is the device implanted?	Х	

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 <u>elizabeth@stimwave.com</u>.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES	PAYMENT IDENTIFICATION NUMBER:				
FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	when the rayment 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					
 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 	 CONTACT NAME Laura Perryman I E-MAIL ADDRESS laura@stimwave.com TELEPHONE NUMBER (include Area code) 480-3717991 S FACSIMILE (FAX) NUMBER (Include Area code) 				
please refer to the application descriptions at the	lationandGuidance/GuidanceDocuments/ucm345263.htm 3.1 Select a center				
 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 [X] NO, I am not a small business the required qualifying documents to FDA 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 app@castionss thenfirst FDMAC SURbit Ottletal Dup	I The sole purpose of the application is to at CDRH-FOISTATUS@tda.hhs.gov or 301-796-8118 Support conditions of use for a bediatric				

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[] 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

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.

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Records r	processed unde	r F()IA Reque	st #2015-5065;	Released by	CDRH on	03-21-2017
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DEPARTMENT OF HEALTH AND HUMAN SERVICES Form Approval FOOD AND DRUG ADMINISTRATION OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.								
Date of Submission	User Fee Payment	ID Number		FDA Submiss	ion Docume	ent Numbe	r (if known)	
05/27/2014	(b)(4)							
SECTION A		TIFE OF SI	UBMISSION					
PMA Original Submission Premarket Report Modular Submission Amendment Report Report Licensing Agreement	PMA & HDE Supplement Regular (180 day) Special Panel Track (PMA Only) 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Amendment to PMA & HDE Supplement Other	PD Original PD Notice of C Amendmen Class II Exemp	OP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP Image: Completion on to PDP		(Complete ige 5) rmation	Pre-S	est for Feedback Submission mational Meeting nision Issue Meeting 100 Meeting ement Meeting rmination Meeting y Risk Determination r (specify): er Submission	
Original Submission Amendment Supplement	Exemption (HDE) Original Submission Amendment Supplement Report Report Amendment	☐ Original Su	ubmission Information	Evaluation of Automatic Class III Designation (De Novo) Original Submission Additional Information		513 Othe	(g)	
Have you used or cited Stand SECTION B	-			please complete Se	ection I, Pag	e 5)		
Company / Institution Name	SUBIN	IIIER, APPLI		Registration Number	(if known)			
Stimwave Technologies Incorp	porated		3010676138					
Division Name (if applicable)			Phone Number (including area code)					
			800-965-5134					
Street Address			FAX Number (i	including area code)				
420 Lincoln Road, Suite 365			800-965-5134					
City			State / Province ZIP/Postal Code Count			Country		
Miami Beach			FL 33139				United States	
Contact Name Elizabeth Greene								
Contact Title			Contact E-mail					
Regulatory Affairs Manager			elizabeth@stin					
SECTION C Company / Institution Name	APPLICATION CORRES	PONDENT (e.	g., consultar	nt, if different from	n above)			
Division Name (if applicable)			Phone Number	r (including area code)			
Street Address		FAX Number (including area code)						
City			State / Provinc	e	ZIP Code		Country	
Contact Name			1					
Contact Title			Contact E-mail	Address				
FORM FDA 3514 (1/13)			1			Pa	age 1 of 5 Pages	

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PSC Publishing Services (301) 443-6740 EF

SECTION D1 REA	SON FOR APPLICATION - PMA, PDP, OR H	IDE
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 Process change: Manufacturing Process change: Other (specify below) Response to FDA correspondence:	 Change in design, component, or specification: Software / Hardware Color Additive Material Specifications Other (specify below) 	Location change: Manufacturer Sterilizer Packager Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment Change in Ownership Change in Correspondent Change of Applicant Address
Other Reason <i>(specify):</i>		
SECTION D2 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	REASON FOR APPLICATION - IDE 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 Hearing
Other Reason <i>(specify):</i>		
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Other Reason (specify): FORM FDA 3514 (1/13)		Page 2 of 5 Pages

SE	SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS											
Pro	oduct codes of devices t	o w										Summary of, or statement concerning, safety and effectiveness information
1	GZB		2			3		4				510 (k) summary attached
5			6			7	1	8				510 (k) statement
Information on devices to which substantial equivalence is claimed (if known)												
			lumber			Trade or Proprietar	vor	Model Nam	9			Manufacturer
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1 Freedom Spinal Cord Stimulator System								1 FRE4-A001				
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	CTION G),F	PRODUCT R. Section (if applicable	CLA e)	S	SIFICATION - APPLI	CAT		ALL ice C		LICA	TIONS
	ZB		2.5880	~/					Cla] Class II
Classification Panel						_		I Class II				
N	Neurology Class III Unclassified											
T th	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.											
FO	RM FDA 3514 (1/1	3)						Auto BANKIN (1997)				Page 3 of 5 Pages
	-	-										

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

Add Continuation Page Page 4 of 5 Pages

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 Addre	255
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FORM FDA 3514 (1/13)

SECTION H	MANUFACTURING / PACKAGING / ST	ERILIZATION SITES RELA	ATING TO A SU	BMISSION	
o)(4)					
					·
Original	Facility Establishment Identifier (FEI) Number	Manufacturer	Contract Steriliz		
Add Delete		Contract Manufacturer		elabeler	
Company / Institution Nam	e	Establishment Registration Num	nber		
Division Name (if applicab	le)	Phone Number (including area of	code)		
Street Address		FAX Number (including area co	de)		
0.1		State / Province	ZIP Code	Count	ry/
City		State / Province	ZIF Gude		'y

ст	ION I		UTILIZATION OF STANDARDS		
	Complete this sec lard" statement.	tion if your application	or submission cites standards or includes a "Declaration of Conform	mity to a Recogniz	ed
	Standards No. 10993-7	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	Version 2008/(R)2012	Date 12-10-2008
	Standards No. 10993-5	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	Version 2009	Date 06-23-2009
	Standards No. 10993-10	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Version 2010	Date 09-10-2010
	Standards No. 10993-11	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 11L Tests for systemic toxicity	Version 2006/(R)2010	Date 10-19-2006
	Standards No. 10993-3	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	Version 2003/(R)2009	Date 01/01/2009
	Standards No. 10993-6	Standards Organization AAMI/ANSI/ISO	Standards Title Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	Version 2007/(R)2010	Date 04-11-2007
	Standards No. 11607-2	Standards Organization AAMI/ANSI/ISO	Standards Title Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	Version 2006/(R)2010	Date 12-23-2005
		Please	include any additional standards to be cited on a separate pag	e.	
	existing data source	*DO NOT SEND r this collection of inf es, gather and maintain	ion applies only to requirements of the Paperwork Reduction Act of 15 YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS formation is estimated to average 0.5 hour per response, including the n the data needed and complete and review the collection of information information collection, including suggestions for reducing this burden Department of Health and Human Services	BELOW.* e time to review in ation. Send comme	nstructions, search ents regarding this

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850

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FORM FDA 3514 (1/13)

			UTILIZATION OF STANDARDS		
te	: Complete this sect dard" statement.	tion if your applicatior	n or submission cites standards or includes a "Declaration of Confor	mity to a Recogniz	red
nc				1	
	Standards No.	Standards Organization	Standards Title	Version	Date
	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
	Standards No.	Standards	Standards Title	Version	Date
	D4169	Organization ASTM	Standard practice for performance testing of shipping containers and systems (Sterility)	2009	11-01-2009
	Standards No.	Standards	Standards Title	Version	Date
	61000-4-2	Organization IEC	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity tests	Ed 2.0 2008	12-01-2008
	Standards No.	Standards	Standards Title	Version	Date
	61000-4-8	Organization IEC	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	Ed. 2.0 2009	09-01-2009
	Standards No. 61000-4-3	Standards Organization	Standards Title Electromagnetic compatibility (EMC) - Part 4.3: Testing and	Version Ed. 3.2 2010	Date
		IEC	measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test		04-01-2010
	Standards No.	Standards	Standards Title	Version	Date
	11	Organization CISPR	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	ED. 5.1B 2010	
					01-27-2011
	Standards No.	Standards Organization ANSI/IEEE	Standards Title	Version	Date
	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
		Please	include any additional standards to be cited on a separate page	e.	
			on applies only to requirements of the Paperwork Reduction Act of 15		******
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			Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850		
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FORM FDA 3514 (1/13)

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

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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		tion if your application	on or submission cites standards or includes a "Declaration of Confo	rmity to a Recog	nized
anc	lard" statement.				
	Standards No.	Standards Organization	Standards Title	Version	Date
	10974	ISO/TS	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	2012	
			with an active implantable incurcal device		10-08-2013
	Standards No.	Standards	Standards Title	Version	Date
		Organization			
	Standards No.	Standards Organization	Standards Title	Version	Date
		Organization			
	Standards No.	Standards	Standards Title	Version	Date
		Organization			
	Standards No.	Standards	Standards Title	Version	Date
		Organization			
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	Standards No.	Standards	Standards Title	Version	Date
		Organization			
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			ction applies only to requirements of the Paperwork Reduction Act of 1		
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			Food and Drug Administration		
			Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff		
			1350 Piccard Drive, Room 400 Rockville, MD 20850		
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FORM FDA 3514 (1/13)

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)



Stimwave Technologies Incorporated Traditional 510(k) Premarket Submission Freedom Spinal Cord Stimulator (SCS) System

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)?	Х	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		Х
Does the device contain components derived from a tissue or other biologic source?		Х
Is the device provided sterile?	Х	
Is the device intended for single use?	Х	
Is the device a reprocessed single use device?		Х
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		Х
Does the device contain a biologic?		Х
Does the device use software?	Х	
Does the submission include clinical information?	Х	
Is the device implanted?	Χ	

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 <u>elizabeth@stimwave.com</u>.

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_ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use (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

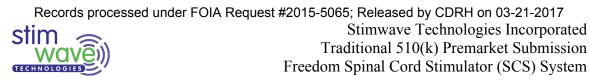
Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Classification Regulation:	882.5880
Product Code:	GZB
Device Class:	Class II
Classification Panel:	Neurology

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.

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

Table 5A. Comparison of Characteristics

Comparator	Stimwave	Medtronic	Medtronic Xtrel,	ANS Renew	
	Freedom SCS	Mattrix 3271/3272	Model Number	(K000852)	
	System	(K934065)	3425 (K883780)		
Stimulator Length	(b)(4)	30 to 110	30 to 110	30 centimeters, and	
		centimeters	centimeters	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		12.25 mm^2	12.25 mm^2	"Approximately 13	
Area				mm ² "	
Method of		Same as Freedom	Same as Freedom	Same as Freedom	
Introduction					
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	
Lucening		Sume us ricedom		Sume us ricedom	
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	50 to 1000	1 to 500	
		microseconds	microseconds	microseconds	
Amplitude (300 Ω)		0 to 7 V	0 to 5.5 V	0 to 20 mA	
Amplitude		0 to 14 V	0 to 10 V	0 to 15 mA	
(500 Ω)					
Amplitude (800 Ω)		0 to 12 V	0 to 8.6 V	0 to 12 mA	
Waveform		Charge Balanced	Charge Balanced	Charge Balanced	
() averonin		Biphasic	Biphasic	(delayed) Biphasic	
		asymmetrical	asymmetrical	asymmetrical	
Pulse Shape		Decaying	Decaying	Decaying	
i uise snape		Exponential	Exponential	Exponential	
Average Current		91.9 mA/cm^2 ,	70.8 mA/cm^2 ,	74.4 mA/cm^2	
Density (300 Ω ,		146.0 mA/cm^2	105.0 mA/cm^2	108.0 mA/cm^2	
500 Ω)					
Charge in 500 µs*		11.7 μC/pulse,	9.2 μC/pulse,	10 μC/pulse,	
$(300 \ \Omega, 500 \ \Omega)$		14.0 μ C/pulse	$10.0 \ \mu C/pulse$	7.5 μ C/pulse	
Charge Density in		$95.2 \mu\text{C/cm}^2$	$74.8 \ \mu C/cm^2$,	$76.9 \mu\text{C/cm}^2$,	
500 μ s* (300 Ω,		$114.3 \ \mu C/cm^2$	$81.6 \mu\text{C/cm}^2$	$57.7 \mu\text{C/cm}^2$	
500 Ω)				- · · · · / · · · ·	
Max Current		190.5 mA/cm^2 ,	149.7 mA/cm^2 ,	153.9 mA/cm^2 ,	
Density* (300 Ω ,		228.6 mA/cm^2	163.3 mA/cm^2	115.4 mA/cm^2	
500 Ω)					
Average Phase		0.135 W/phase,	0.080 W/phase,	0.074 W/phase,	
Power		0.172 W/phase	0.088 W/phase	0.094 W/phase	
(300 Ω, 500 Ω)			_	_	
Average Phase		0.50 W/cm ² /phase,	0.31 W/cm ² /phase,	0.29 W/cm ² /phase,	
Power Density		1.36 W/cm ² /phase	0.69 W/cm ² /phase	0.74 W/cm ² /phase	
(300 Ω, 500 Ω)			_	_	
			•	·I	

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

9. Non-Clinical Performance Data





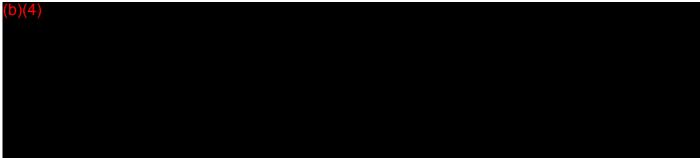
10. Clinical Performance Data



11. Statement of Substantial Equivalence



Section 6 – Truthful and Accurate Statement



Page 6-1 of 1

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.

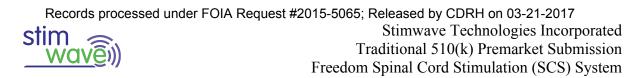
Section 10 - Executive Summary

Device Name: Freedom Spinal Cord Stimulation (SCS) System

Device Name Classification Name: Trade/Proprietary Name: Common/Usual Name: Model Number(s):	Stimulator, Spinal-Cord, Implanted (Pain Relief) Freedom Spinal Cord Stimulation (SCS) System Spinal Cord Stimulator Receiver: FRE4-A001, Receiver Kit: FRE4-A000, Trial: FRT4-A001, Trial Kit: FRT4-A000, Wearable Antenna Assembly: WAA-A012, Wearable Antenna Assembly
Regulation Number: Classification Panel: Product Code: Device Class: FDA Establishment Number:	Kit: WAA-A011 882.5880 Neurology GZB 2 Not Applicable
Reason:	This is the original submission for this device.
Predicate Devices	
510(k) Number: Trade Name: Classification Product Code:	K934065 Medtronic Mattrix 3271/3272 Neuromodulation System GZB and GZF
510(k) Number: Trade Name: Classification Product Code:	K883780 Medtronic Xtrel, Model Number 3425 Receiver GZB
510(k) Number: Trade Name:	K000852 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

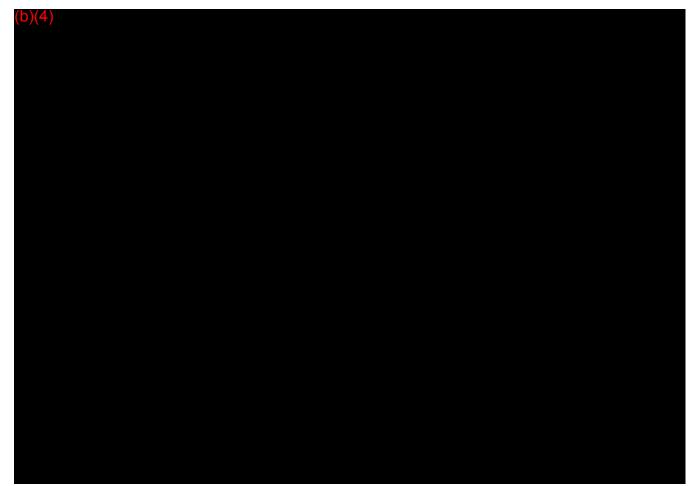


Table 10A. Patient Contacting Materials

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

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Stimwave Technologies Incorporated Traditional 510(k) Premarket Submission Freedom Spinal Cord Stimulation (SCS) System

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.

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- 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.

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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.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- 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.

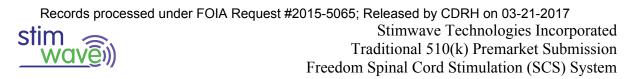
Bone growth stimulators – Do not use a magnetic field bone growth stimulator coils within the vicinity of the Freedom SCS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient. If a bone growth stimulator must be used, remove the WAA from the patient and ensure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



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.

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

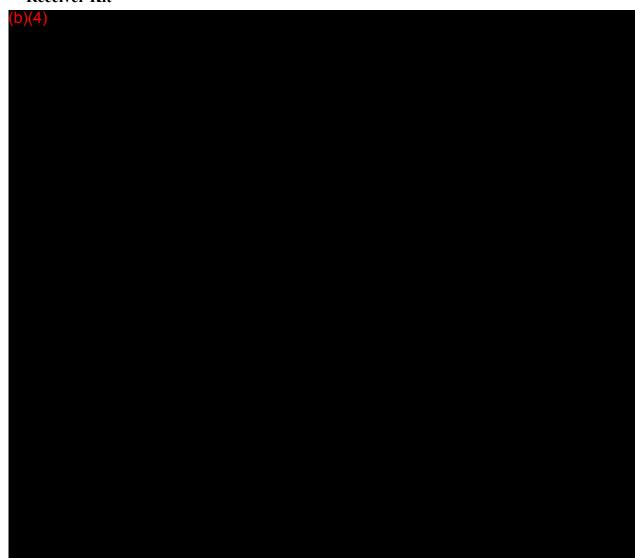
 Table 10B. Comparison of the Stimwave Freedom SCS System to predicate devices

Comparator	Stimwave Freedom SCS System	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Labeling	(b)(4)	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	50 to 1000	1 to 500
		microseconds	microseconds	microseconds
Amplitude		0 to 7 V	0 to 5.5 V	0 to 20 mA
(300 Ω)				
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	Charge Balanced	Charge Balanced
		Biphasic	Biphasic	(delayed) Biphasic
		asymmetrical	asymmetrical	asymmetrical
Pulse Shape		Decaying	Decaying	Decaying
		Exponential	Exponential	Exponential
Average		91.9 mA/cm ² ,	70.8 mA/cm^2 ,	74.4 mA/cm ² ,
Current Density		146.0 mA/cm^2	105.0 mA/cm^2	108.0 mA/cm^2
(300 Ω, 500 Ω)				
Charge in 500		11.7 μ C/pulse,	9.2 μ C/pulse,	10 μC/pulse,
μs*		14.0 µC/pulse	10.0 µC/pulse	7.5 μC/pulse
(300 Ω, 500 Ω)		$05.2 - C/m^2$	74.9 0/2	$7(0, 0/m^2)$
Charge Density		95.2 μC/cm ² , 114.3 μC/cm ²	74.8 μ C/cm ² , 81.6 μ C/cm ²	76.9 μ C/cm ² , 57.7 μ C/cm ²
in 500 μs* (300 Ω, 500 Ω)		114.5 μ C/cm	81.0 µC/cm	57.7 μC/cm
Max Current		190.5 mA/cm^2 ,	149.7 mA/cm^2 ,	153.9 mA/cm^2 ,
Density* (300 Ω ,		228.6 mA/cm^2	149.7 mA/cm^2 163.3 mA/cm ²	115.4 mA/cm^2
500 Ω)		220.0 m/ 4/ cm		110.4 m/ t/cm
Average Phase		0.135 W/phase,	0.080 W/phase,	0.074 W/phase,
Power		0.172 W/phase	0.088 W/phase	0.094 W/phase
(300 Ω, 500 Ω)		1	1	1
Average Phase		0.50 W/cm ² /phase,	0.31 W/cm ² /phase,	0.29 W/cm ² /phase,
Power Density		1.36 W/cm ² /phase	0.69 W/cm ² /phase	0.74 W/cm ² /phase
(300 Ω, 500 Ω)				
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,	Coupling receiver,	Coupled receiver,
		Radio Frequency	Radio Frequency	hardwired with
		transmission	transmission	connector
Material		Same as Freedom	Same as Freedom	Same as Freedom
			I	1

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

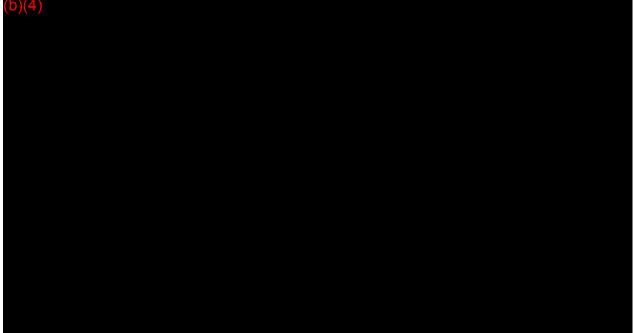
(*) asterisk denotes that formulas were used for the calculations.

Technology Receiver Kit

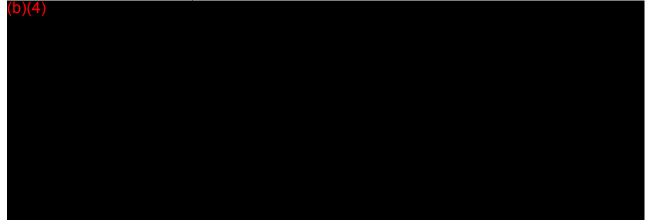




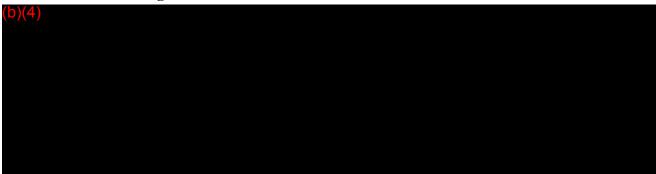
WAA Kit



Performance Summary



Mechanical Testing



Environmental Testing

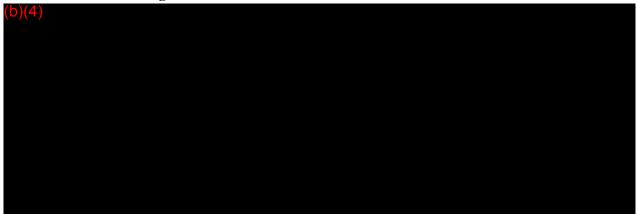
b)(4)

(b)(4)			

Electrical Testing

(b)(4)			



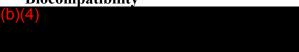








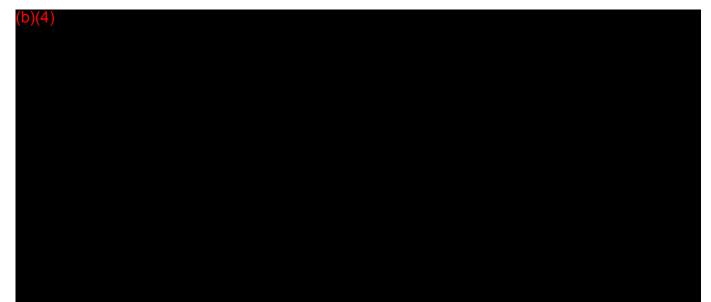
Biocompatibility



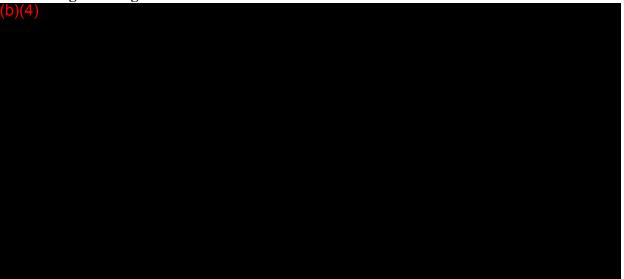


Software Verification and Validation

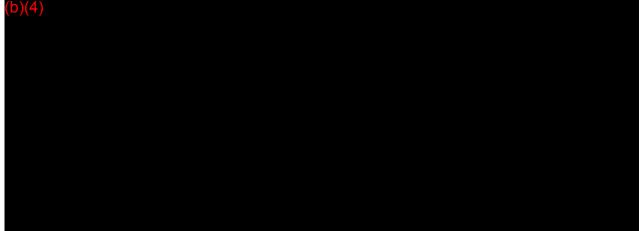
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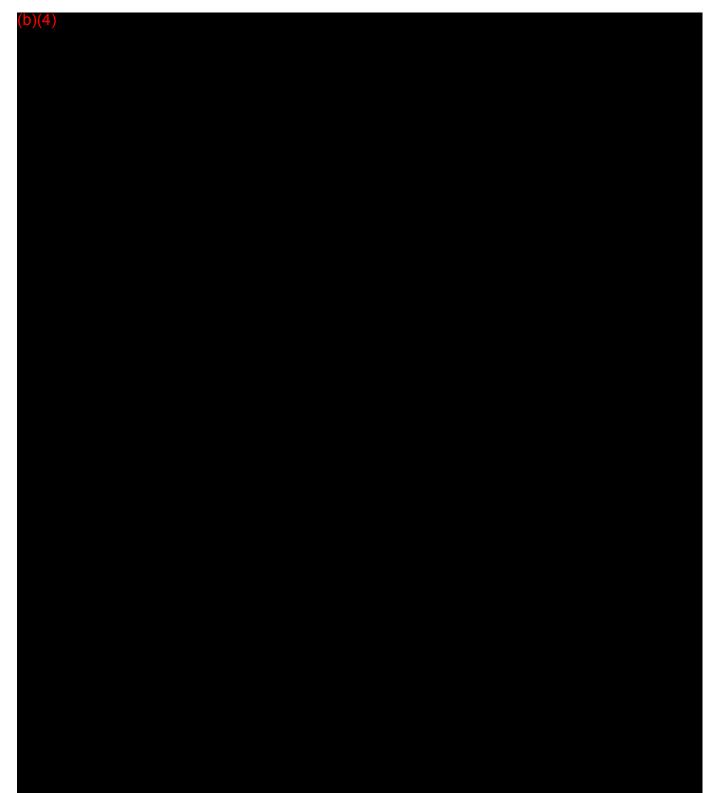


Package Testing







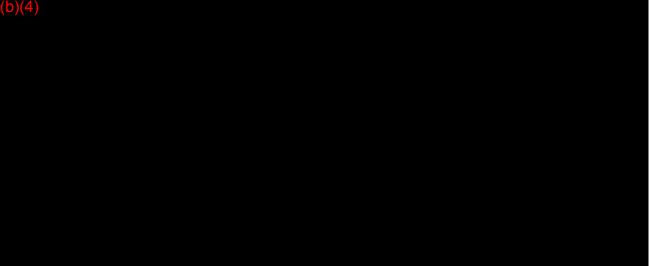


Section 14 – Sterilization and Shelf Life

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Discussion Summary (b)(4)

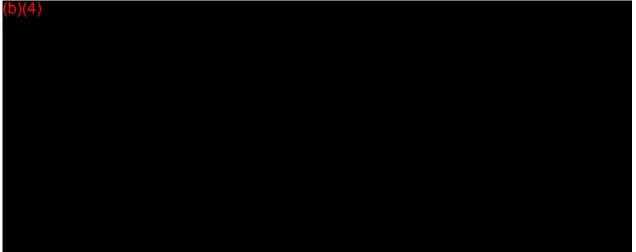
Validation Method of Sterilization Process







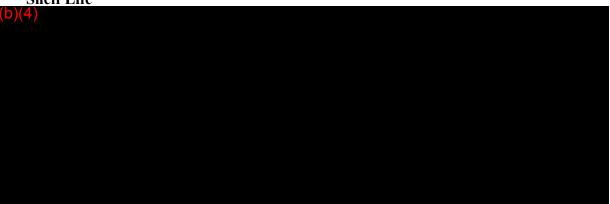
Pyrogenicity Testing

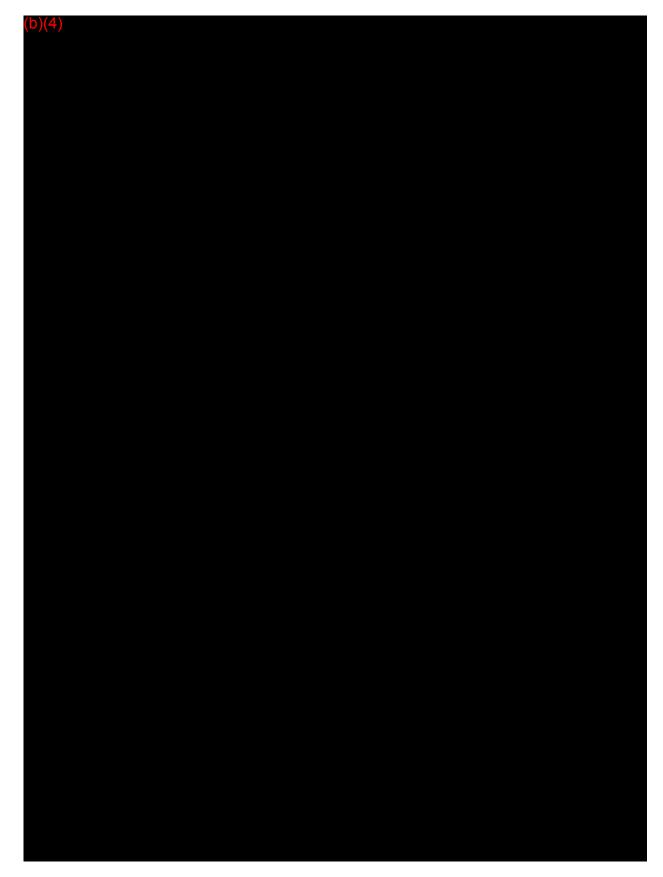


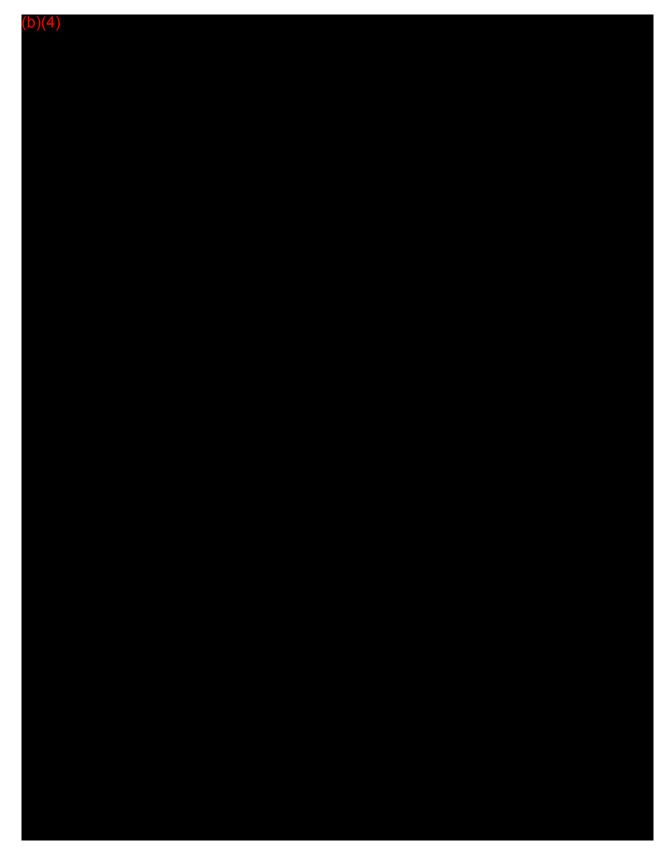
Bioburden Testing

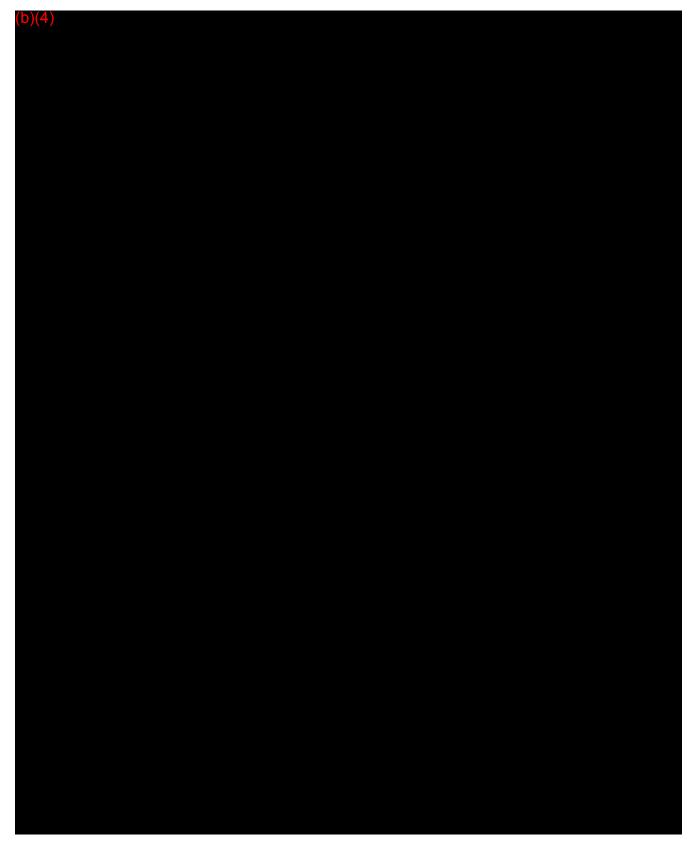
(b)(4)	8	







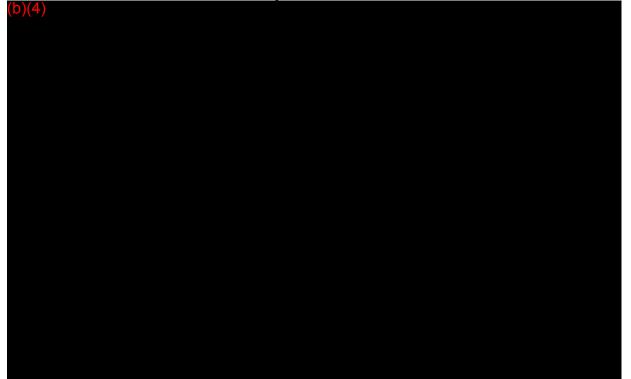






Sterilization and Shelf Life Summary

(b)(4)

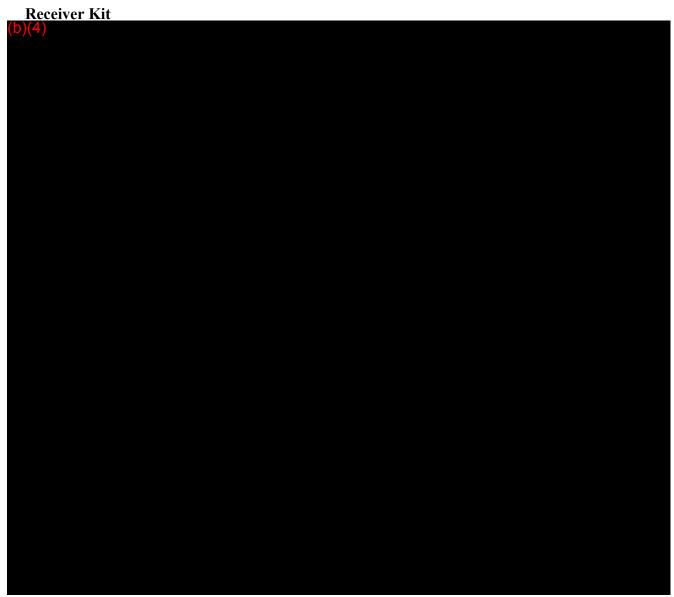


Packaging and Stability Summary





Test Reports	Exhibits
(b)(4)	

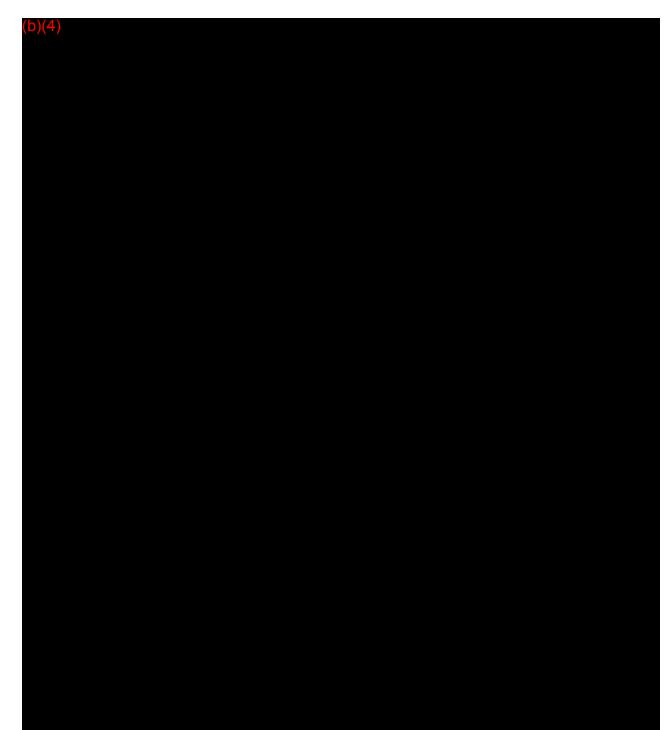


(b)(4)

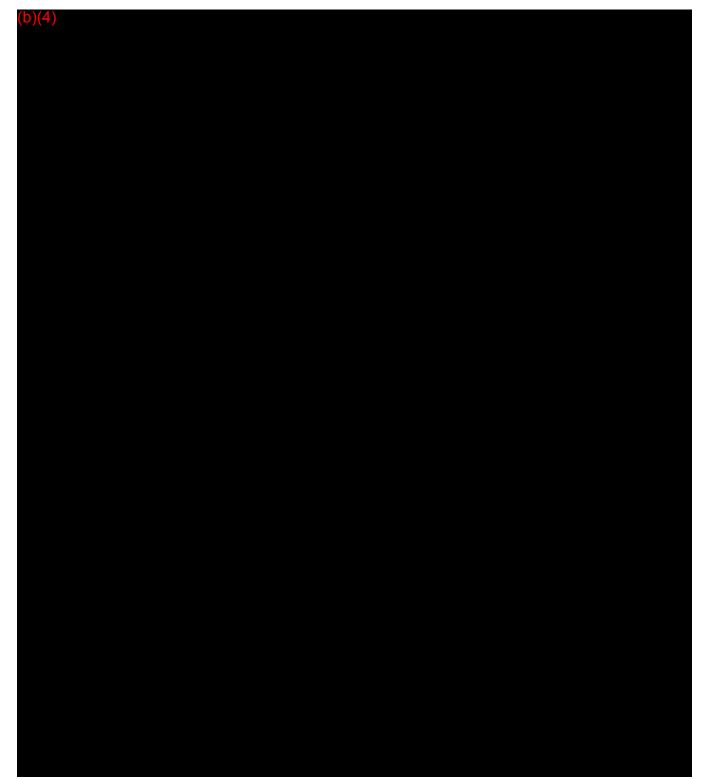
Wearable Antenna Assembly (WAA) Kit

wearable Antenna Assembly (wAA) Ku	
(b)(4)	





Section 15 – Biocompatibility



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Implant Categorization



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Evaluation Tests



Biocompatibility Testing



Page 15-3 of 13





Samples for Biocompatibility

(b)(4)		

Page 15-4 of 13







Sensitization



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b)(4)

Irritation and Intracutaneous Reactivity



Acute Systemic Toxicity

(b)(4)			

Genotoxicity

b)(4)

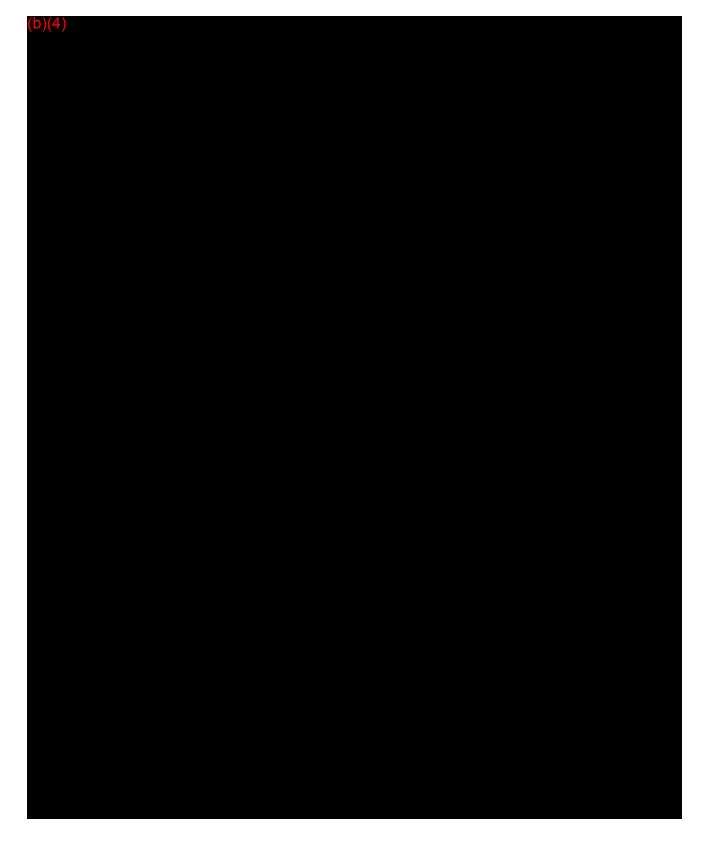
Page 15-6 of 13





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Page 15-8 of 13





Implantation

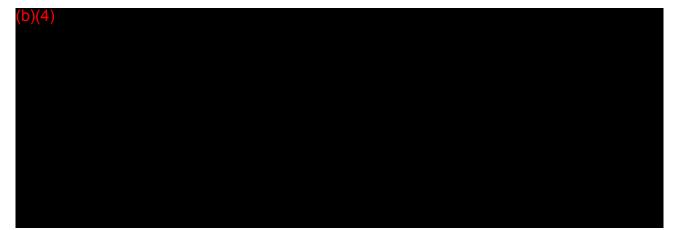


Subchronic Toxicity

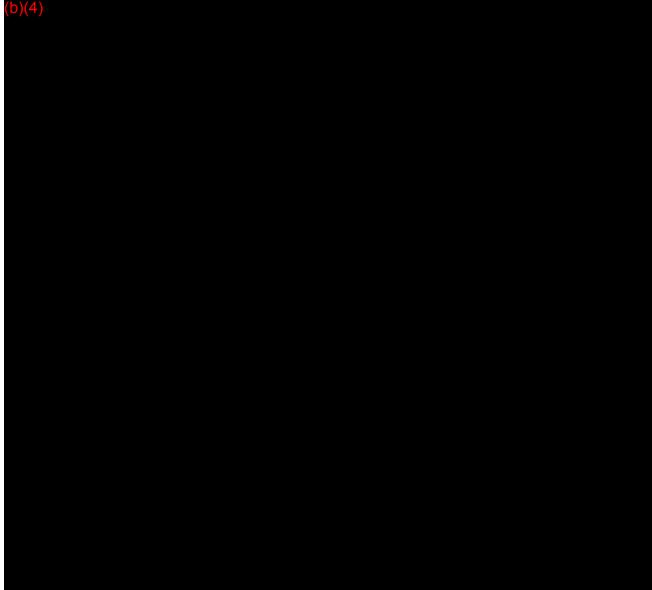


Page 15-9 of 13



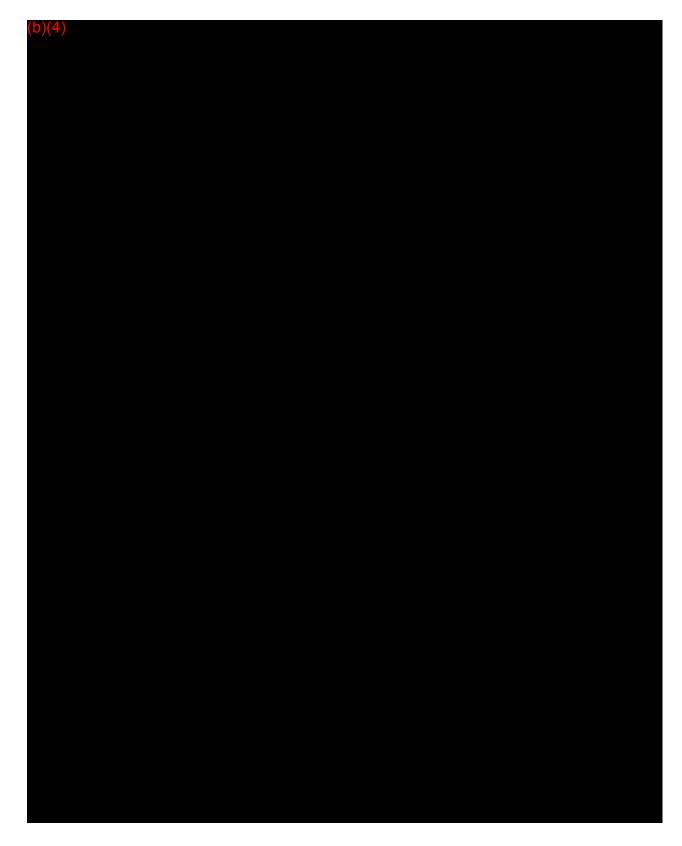


Chronic, and Carcinogenicity



Page 15-10 of 13





Page 15-11 of 13



b)(4)

Manufacturing, Packaging, and Sterilization Considerations

Page 15-12 of 13





Biocompatibility of the WAA

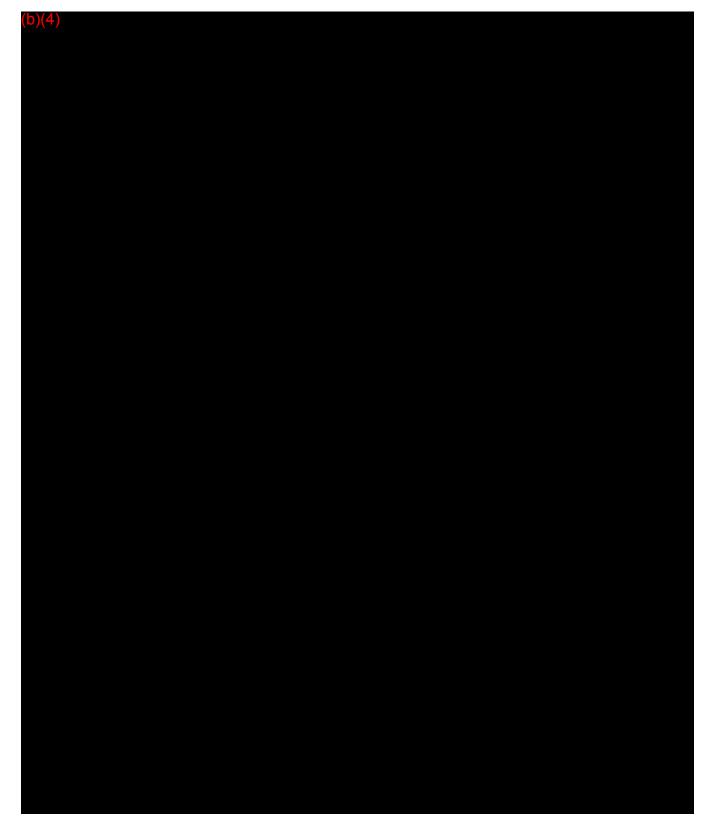


Conclusion



Page 15-13 of 13

Section 16 - Software and Firmware



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Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017

	Form Approved: OMB No. 0910-0120; Exp	piration Da	te: 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 be ences a national or international standard. A separate report is requ	by the applicant when submitting a	510(k) th n the 51	nat refer- 0(k).
	Abbreviated		
STANDARD TITLE ¹ AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices	s - Part 1: Evaluation and testing within	a risk ma	nagement
Please answer the following questions		Yes	No
Is this standard recognized by FDA ² ?		×	
FDA Recognition number ³		<u>2-156</u>	
Was a third party laboratory responsible for testing conformity of the in the 510(k)?	ne device to this standard identified		
Is a summary report ⁴ describing the extent of conformance of the s 510(k)? If no, complete a summary report table.			
Does the test data for this device demonstrate conformity to the req pertains to this device?	quirements of this standard as it	X	
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X	
Does this standard include more than one option or selection of test If yes, report options selected in the summary report table.	sts?		X
Were there any deviations or adaptations made in the use of the sta If yes, were deviations in accordance with the FDA supplemental in	andard? nformation sheet (SIS) ⁵ ?		
Were deviations or adaptations made beyond what is specified in the If yes, report these deviations or adaptations in the summary report			×
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 51 Title of guidance: <u>FDA Bluebook Memorandum G95-1</u> "Use of Internation	10k?	X	
[title of standard] [date of publication] standard] 2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html utilized 3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/ 5 The su 4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); 6 The on 6 The on 6 The on	cation body involved in conformance assessmen ard. The summary report includes information on d during the development of the device. upplemental information sheet (SIS) is additional is necessary before FDA recognizes the standa www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfSi h.cfm nline search for CDRH Guidance Documents can fda.gov/cdrh/guidance.html	all standa I informatio rd. Found tandards/	n at

FORM FDA 3654 (12/10)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
STANDARD TITLE AAMI/ANSI/ISO 10	STANDARD TITLE AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management			
	CONFORMANCE WITH S	STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
ALL	ALL		Yes 🗌 No 🗌 N/A	
TYPE OF DEVIATION C	R OPTION SELECTED *		25	
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
			Yes No N/A	
TYPE OF DEVIATION C	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION O			Yes No N/A	
TYPE OF DEVIATION C	R 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. 				
	Paperwork Reduct			
time for review completing and	g burden for this collection of information is ving instructions, searching existing data sour d reviewing the collection of information. Ser ollection of information, including suggestion	ces, gathering and maintaining the data comments regarding this burden e	ata needed, and	
Food Office 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it	

FORM FDA 3654 (12/10)

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017

Form Approved: OMB No. 0910-0120; Ex	piration Da	ate: 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 ences a national or international standard. A separate report is required for each standard referenced				
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 steril	ization re	siduals		
AAMI/ANSI/ISO 10995-1.2006(R)2012 Biological evaluation of medical devices – 1 at 7. Eurytene oxide stern		5144415		
Please answer the following questions	Yes	No		
Is this standard recognized by FDA ² ?	×			
FDA Recognition number ³	# <u>14-278</u>			
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.	X			
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	X			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X		
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	X			
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 ?		□ X		
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.		X		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X		
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: <u>Blue Book Memorandum #G95-1</u>	X			
 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [ittle 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 ⁶ The online search for CDRH Guidance Documents www.fda.gov/cdrh/guidance.html 	on all stand nal informat dard. Foun fStandards	tion d at /		

FORM FDA 3654 (12/10)

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	Form Approved: OMB No. 0910-0120; Exp	iration Da	ate: 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 comp ences a national or international standard. A separate report	leted by the applicant when submitting a s is required for each standard referenced in	510(k) t n the 51	hat refer- I0(k).	
TYPE OF 510(K) SUBMISSION	Abbreviated			
STANDARD TITLE ¹ AAMI/ANSI/ISO 10993-5:2009 Biological evaluation of medical d	levices – Part 5: Tests for In Vitro cytotoxicity			
Please answer the following questions		Yes	No	
Is this standard recognized by FDA 2?		X		
FDA Recognition number ³		2-153		
Was a third party laboratory responsible for testing conformit in the 510(k)?		\times		
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.		\boxtimes		
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 If yes, report options selected in the summary report table.	n of tests?		X	
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA supplem				
Were deviations or adaptations made beyond what is specifi If yes, report these deviations or adaptations in the summary			\boxtimes	
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\mathbf{X}	
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation o Title of guidance: FDA Bluebook Memorandum G95-1 "Use of I	f this 510k?	XX		
 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 ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm 	address of the test laboratory or certification body invo assessment to this standard. The summary report incl all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additiona is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda	udes infor vice. I informati und at http	mation on on which o://	
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 ⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm				

FORM FDA 3654 (6/11)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE					
STANDARD TITLE AAMI/ANSI/ISO 10	STANDARD TITLE AAMI/ANSI/ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity				
	CONFORMANCE WIT	TH STANDARD SECTIONS*			
SECTION NUMBER ALL	SECTION TITLE ALL	CONFORMANCE?			
TYPE OF DEVIATION (DR OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE	CONFORMANCE?			
TYPE OF DEVIATION (DR OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE	CONFORMANCE? Yes No			
TYPE OF DEVIATION (DR 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.					
Paperwork Reduction Act Statement					
Public reporting burden for this collection of information is estimated to average 1 hour 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:					
Department of Health and Human ServicesFood and Drug AdministrationOffice of Chief Information Officer1350 Piccard Drive, Room 400Rockville, MD 20850					

FORM FDA 3654 (6/11)

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017

Form	Approved	OMP No	0010-0120-	Evniration	Date: 12/31/13
FUIII	Approveu.	UNID NO.	0910-0120,	LADITATION	Date. 12/01/10

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 complences a national or international standard. A separate report				
TYPE OF 510(K) SUBMISSION	Abbreviated			
STANDARD TITLE ¹ AAMI/ANSI/ISO 10993-10:2010 Biological Evaluation of Medical	Devices - Part 10: Test for Irritation and Skin	Sensitiz	ation	
Please answer the following questions		Yes	No	
Is this standard recognized by FDA 2?		\boxtimes		
FDA Recognition number ³		<u></u> ¥2-173		
Was a third party laboratory responsible for testing conformit in the 510(k)?		\boxtimes		
Is a summary report ⁴ describing the extent of conformance of 510(k)? If no, complete a summary report table.		\boxtimes		
Does the test data for this device demonstrate conformity to pertains to this device?		\boxtimes		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\boxtimes		
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?			
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA supplem				
Were deviations or adaptations made beyond what is specifi If yes, report these deviations or adaptations in the summary			\boxtimes	
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes	
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation o Title of guidance: FDA Bluebook Memorandum G95-1 "Use of I	f this 510k?	X		
 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 ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm 	address of the test laboratory or certification body inva assessment to this standard. The summary report inc all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. Fo www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda	ludes infor evice. al information of http://www.com/ ound at http://www.com/	mation on on which o://	
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 ⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/default.htm				

FORM FDA 3654 (6/11)

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	EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE			
STANDARD TITLE AAMI/ANSI/ISO 10	STANDARD TITLE AAMI/ANSI/ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Test for Irritation and Skin Sensitization			
	CONFORMANCE W	ITH STANDARD SECTIONS*		
SECTION NUMBER ALL	SECTION TITLE ALL		CONFORMANCE? X Yes No N/A	
TYPE OF DEVIATION (DR OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION (DR OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION (DR OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
explanation is need described and adeq selected when follow	ed under "justification." Some standards i uately justified as appropriate for the sub	e whether conformance is met. If a section nclude options, so similar to deviations, th ject device. Explanation of all deviations of f deviation or option selected," "description	e option chosen needs to be or description of options	
* 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 Re	duction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour 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:				
Department of Health and Human ServicesFood and Drug AdministrationOffice of Chief Information Officer1350 Piccard Drive, Room 400Rockville, MD 20850				

FORM FDA 3654 (6/11)

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-	-2017	
Form Approved: OMB No. 0910-0120; Exp	piration Da	te: 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 ences a national or international standard. A separate report is required for each standard referenced	510(k) ti in the 51	nat refer- 0(k).
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 Systemi	c Toxcity	7
Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	\boxtimes	
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)?	\boxtimes	
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	\boxtimes	

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?	\boxtimes	
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes	
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes
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.		\boxtimes
Were there any exclusions from the standard?		\boxtimes

If yes, report these exclusions in the summary report table. Is there an FDA guidance 6 that is associated with this standard?..... \times If yes, was the guidance document followed in preparation of this 510k? X 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

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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/default.htm

FORM FDA 3654 (6/11)

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	EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE			
STANDARD TITLE AAMI/ANSI/ISO 109	993-11:2006/(R)2010 Biological Evaluation	ion of Medical Devices - Part 11: Tests fo	or Systemic Toxcity	
	CONFORMANCE WI	TH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE ALL		CONFORMANCE?	
TYPE OF DEVIATION C	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION C	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION C	R 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. 				
Paperwork Reduction Act Statement				
Public reporting burden for this collection of information is estimated to average 1 hour 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:				
Department of Health and Human ServicesFood and Drug AdministrationOffice of Chief Information Officer1350 Piccard Drive, Room 400Rockville, MD 20850				

Low	Americade	OMD No.	0010 0120.	Evolitation	Data: 12/21/1	2
FOIIII	Approved.	UND NO.	0910-0120.	Expiration	Date: 12/31/1	5

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 ences a national or international standard. A separate report is required for each standard referenced					
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 genotoxicit	y, carcin	ogenicity,			
Please answer the following questions	Yes	No			
Is this standard recognized by FDA ² ?	\boxtimes				
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)?	\boxtimes				
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.	\boxtimes				
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\boxtimes				
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes				
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		X			
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.		X			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X			
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"	\boxtimes				
 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 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 	ludes infor evice. al informati ound at http ards/searcl an be found	mation on on which b:// h.cfm d at			

FORM FDA 3654 (6/11)

PSC Publishing Services (301) 443-6740 EF

		ANDARD CONFORMANCE RY REPORT TABLE	
STANDARD TITLE AAMI/ANSI/ISO 109	993-3:2003/(R)2009 Biological evaluat	ion of medical devices – Part 3: Tests for g	genotoxicity, carcinogenicity,
	CONFORMANCE V	WITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE ALL		CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is neede described and adeque selected when follow	ed under "justification." Some standards uately justified as appropriate for the su	te whether conformance is met. If a section include options, so similar to deviations, the bject device. Explanation of all deviations of of deviation or option selected," "description	e option chosen needs to be or description of options
		the standard, a deviation brought out by the the device, or any adaptation of a section.	
	Paperwork R	eduction Act Statement	
time for review completing and	ving instructions, searching existing dat	tion is estimated to average 1 hour per resp ta sources, gathering and maintaining the d on. Send comments regarding this burden e gestions for reducing this burden to:	ata needed, and
Food Office 1350	tment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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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)						
This report and the Summary Report Table are to be comple ences a national or international standard. A separate report i	eted by the applicant when submitting a 5 is required for each standard referenced in	510(k) th n the 51	at refer- 0(k).			
TYPE OF 510(K) SUBMISSION	Abbreviated					
			1			
STANDARD TITLE ' AAMI/ANSI/ISO 10993-6:2007/(R)2010 Biological evaluation of m	edical devices – Part 6: Tests for local effects	s after un	plantation			
Please answer the following questions		Yes	No			
Is this standard recognized by FDA 2?		\times				
FDA Recognition number ³		¥ <u>14-278</u>				
Was a third party laboratory responsible for testing conformit in the 510(k)?	v of the device to this standard identified	\times				
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).		\boxtimes				
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?		\boxtimes			
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA supplem	f the standard? ental information sheet (SIS) ⁵ ?		\square			
Were deviations or adaptations made beyond what is specified of the summary of th	ied in the FDA SIS? y report table.		\boxtimes			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes			
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance: FDA Bluebook Memorandum G95-1 "Use of D	of this 510k?	X				
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]	¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] address of the test laboratory or certification body involved in conformation on all standards utilized during the development of the device.					
 ² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Standards/default.htm ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm 	5 The supplemental information sheet (SIS) is addition is necessary before FDA recognizes the standard. F www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStan	ound at m	(p.//			
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	6 The online search for CDRH Guidance Documents http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	can be fou	nd at			

FORM FDA 3654 (6/11)

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		ARD CONFORMANCE EPORT TABLE				
STANDARD TITLE AAMI/ANSI/ISO 109	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 ALL		CONFORMANCE?			
TYPE OF DEVIATION O	R OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION O	R OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORMANCE?			
TYPE OF DEVIATION O	R OPTION SELECTED *		5.			
DESCRIPTION						
JUSTIFICATION						
explanation is neede described and adequ selected when follow	t all sections of the standard and indicate wh d under "justification." Some standards inclu lately justified as appropriate for the subject ing a standard is required under "type of dev le page may be necessary.	de options, so similar to deviations, th device. Explanation of all deviations o	e option chosen needs to be r description of options			
	can include an exclusion of a section in the s S), a deviation to adapt the standard to the					
	Paperwork Reduc	tion Act Statement				
time for review completing and	g burden for this collection of information is ing instructions, searching existing data sour reviewing the collection of information. Se pollection of information, including suggestion	rces, gathering and maintaining the dand comments regarding this burden e	ata needed, and			
Food a Office 1350 I	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 rille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it			

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13				
Department of Health ar Food and Drug Ar STANDARDS DATA RE (To be filled in b	dministration EPORT FOR 510(k)s by applicant)			
This report and the Summary Report Table are to be completences a national or international standard. A separate report is	ted by the applicant when submitting a 5 s required for each standard referenced in	510(k) th n the 51	nat refer- 0(k).	
TYPE OF 510(K) SUBMISSION				
Traditional Special	Abbreviated			
STANDARD TITLE ¹ AAMI/ANSI/ISO 11607-1:2006/(R) 2010 Packaging for terminally s	sterilized medical devices - Part 1: Requireme	ents for r	naterials ₊	
		Yes	No	
Please answer the following questions		×		
Is this standard recognized by FDA ² ?				
FDA Recognition number ³		<u>‡ 14-193</u>		
Was a third party laboratory responsible for testing conformity in the 510(k)?	of the device to this standard identified	X		
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).		X		
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	of tests?	X		
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA suppleme	the standard? ental information sheet (SIS) ⁵ ?			
Were deviations or adaptations made beyond what is specifie If yes, report these deviations or adaptations in the summary	ed in the FDA SIS? report table.		X	
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X		
Is there an FDA guidance ⁶ that is associated with this standa If yes, was the guidance document followed in preparation of Title of guidance: <u>Premarket Notification [510(k)]</u> Submissions for	f this 510k?	n 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 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 assessm standard. The summary report includes information utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additio which is necessary before FDA recognizes the stan http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ search.cfm ⁶ The online search for CDRH Guidance Documents www.fda.gov/cdrh/guidance.html	ent to this on all star nal inform dard. Fou ofStandard	ndards ation und at Is/	

		NDARD CONFORMANCE Y REPORT TABLE	
STANDARD TITLE			
AAMI/ANSI/ISO 11	607-1:2006/(R) 2010 Packaging for term	inally sterilized medical devices - Part 1	: Requirements for materials
	CONFORMANCE W	TH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE? Yes No
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	OR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is need described and adeq selected when follow report. More than o	st all sections of the standard and indicate ed under "justification." Some standards in uately justified as appropriate for the subj wing a standard is required under "type of ne page may be necessary. can include an exclusion of a section in th	nclude options, so similar to deviations, the ect device. Explanation of all deviations of deviation or option selected," "description	ne option chosen needs to be or description of options n" and "justification" on the
	SIS), a deviation to adapt the standard to t		
	Paperwork Re	duction Act Statement	
time for review completing an	ng burden for this collection of informatic wing instructions, searching existing data d reviewing the collection of information collection of information, including sugge	sources, gathering and maintaining the d	lata needed, and
Food Offic 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spor required to respond to, a collection displays a currently valid OMB cor	of information unless it

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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)					
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) tl in the 51	nat refer- 0(k).			
TYPE OF 510(K) SUBMISSION					
STANDARD TITLE ¹ AAMI/ANSI/ISO 11607-2:2006/(R)2010 Packaging for terminally sterilized medical devices – Part 2: Validation	requirer	nents for f			
Please answer the following questions	Yes	No			
Is this standard recognized by FDA ² ?	\times				
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)?		\boxtimes			
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.	\boxtimes				
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\boxtimes				
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes				
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes			
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.		\mathbf{X}			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		\boxtimes			
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 is	M	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 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, afternative 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 ^a The summary report should include: any adaptations used to adapt to the device under review (for example, afternative 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 	ncludes inf device. mal informa Found at h idards/sea can be fou	ation which ttp:// rch.cfm und at			

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		NDARD CONFORMANCE	
STANDARD TITLE AAMI/ANSI/ISO 11	607-2:2006/(R)2010 Packaging for termin	nally sterilized medical devices - Part 2:	Validation requirements for f
	CONFORMANCE WI	TH STANDARD SECTIONS*	
SECTION NUMBER ALL	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			-
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	at all sections of the standard and indicate ad under "justification." Some standards in uately justified as appropriate for the subje- ving a standard is required under "type of ne page may be necessary. can include an exclusion of a section in th	clude options, so similar to deviations, th act device. Explanation of all deviations o deviation or option selected," "description e standard, a deviation brought out by th	e option chosen needs to be r description of options " and "justification" on the
Information sheet (S	IS), a deviation to adapt the standard to the stan		
time for review	Paperwork Red ag burden for this collection of information ving instructions, searching existing data s d reviewing the collection of information. collection of information, including sugges	sources, gathering and maintaining the da Send comments regarding this burden es	ata needed, and
Food Office 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB cond	of information unless it

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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						
AAMI ANSI ISO III	CONFORMANCE WITH S	Construction of the second	ments for u	le develo	opinein, v	
SECTION NUMBER	SECTION TITLE	TANDARD SECTIONS	CONFORM	ANCE?		
ALL	ALL		Yes	No	□ N/A	
TYPE OF DEVIATION OF	R OPTION SELECTED *	an an ann an				
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE	n of an and a start of the second of the second	CONFORM	IANCE?		
			Yes	🗌 No	□ N/A	
TYPE OF DEVIATION OF	ROPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		CONFORM	IANCE?	-	
			Yes	No	□ N/A	
TYPE OF DEVIATION OF	ROPTION 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.						
	an include an exclusion of a section in the sta S), a deviation to adapt the standard to the de			olementa	l	
	Paperwork Reducti	on Act Statement				
time for review completing and	burden for this collection of information is ing instructions, searching existing data source reviewing the collection of information. Sen ellection of information, including suggestion	ces, gathering and maintaining the da d comments regarding this burden es	ata needed,	and		
Food a Office 1350 F	ment of Health and Human Services nd Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of informatio			

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 comp ences a national or international standard. A separate repor					
TYPE OF 510(K) SUBMISSION					
Traditional Special	Abbreviated				
STANDARD TITLE ¹ AAMI/ANSI/ISO 11737-1:2006 (R)2011 Sterilization of medical d	levices – Microbiological methods Part 1: Dete	rminatio	n of the p		
Please answer the following questions		Yes	No		
Is this standard recognized by FDA 2?		\boxtimes			
FDA Recognition number ³		¥14-227			
Was a third party laboratory responsible for testing conformi in the 510(k)?		\boxtimes			
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.		\boxtimes			
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).		\boxtimes			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?		\boxtimes		
Were there any deviations or adaptations made in the use o If yes, were deviations in accordance with the FDA supplem					
Were deviations or adaptations made beyond what is specifing lf yes, report these deviations or adaptations in the summary			\boxtimes		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes		
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation o 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 	address of the test laboratory or certification body invo assessment to this standard. The summary report incl all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additiona	udes inforr vice.	mation on		
³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	is necessary before FDA recognizes the standard. For www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda	und at http	://		
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	6 The online search for CDRH Guidance Documents ca http://www.fda.gov/MedicalDevices/DeviceRegulationa GuidanceDocuments/default.htm	n be found	at		

FORM FDA 3654 (6/11)

	EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE				
STANDARD TITLE AAMI/ANSI/ISO 117	37-1:2006 (R)2011 Sterilization of medical of	levices – Microbiological methods Pa	art 1: Deter	minatior	of the p
	CONFORMANCE WITH S	TANDARD SECTIONS*			
SECTION NUMBER	SECTION TITLE			ANCE?	□ N/A
TYPE OF DEVIATION O	R OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE				
TYPE OF DEVIATION O	R OPTION SELECTED *		Yes	No No	<u>N/A</u>
DESCRIPTION	-				
JUSTIFICATION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	□ N/A
TYPE OF DEVIATION O	R 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. 					
	Paperwork Reduct				
Public reporting burden for this collection of information is estimated to average 1 hour 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:					
Food a Office 1350 I	tment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of informatic		

	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 ences a national or international standard. A separate report is required for each standard referenced i	510(k) th n the 51	at refer- 0(k).	
Т	YPE OF 510(K) SUBMISSION			
	Traditional Special Abbreviated			
S	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 ?	\boxtimes		
-	FDA Recognition number ³	<u>#14-300</u>		
	Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	\boxtimes		
	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.	\boxtimes		
	Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\times		
	Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes		
and the second se	Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes	
	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.		\boxtimes	
and the second se	Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		\boxtimes	
	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:		\mathbf{X}	
	address of the test laboratory or certification body in	volved in c	onformance	
and the second se	standard] [date of publication] all standards utilized during the development of the	device.	mation on	
	² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Standards/default.htm 5 The supplemental information sheet (SIS) is addition is necessary before FDA recognizes the standard. If is necessary before FDA recognizes the standard.	-ound at m	(p.//	
	 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, atternative 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 The online search for CDRH Guidance Documents http://www.fda.gov/MedicalDevices/DeviceRegulati 	can be fou	nd at	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE			
STANDARD TITLE ASTM D4169-09, Sta	ndard practice for performance testing of ship	ping containers and systems. (steril	ity)	
	CONFORMANCE WITH S	TANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE ALL			
TYPE OF DEVIATION O	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION O	R OPTION SELECTED *]	
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION O	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
explanation is neede described and adequ selected when follow	t all sections of the standard and indicate whe d under "justification." Some standards include uately justified as appropriate for the subject de ring a standard is required under "type of devia ne page may be necessary.	e options, so similar to deviations, the evice. Explanation of all deviations of	e option chosen needs to be or description of options	
* Types of deviations of information sheet (S	can include an exclusion of a section in the sta IS), a deviation to adapt the standard to the de	andard, a deviation brought out by the avice, or any adaptation of a section	e FDA supplemental	
	Paperwork Reducti	on Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour 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:				
Food Office 1350	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it	

FORM FDA 3654 (6/11)

	Form Approved: OMB No. 0910-0120; Exp	piration Da	te: 12/31/13
Department of Health a Food and Drug A STANDARDS DATA R (To be filled in	Administration EPORT FOR 510(k)s		
This report and the Summary Report Table are to be comple ences a national or international standard. A separate report i			
TYPE OF 510(K) SUBMISSION			
Traditional Special	Abbreviated		
STANDARD TITLE ¹ AAMI/ANSI/ISO 14708-3:2008-01-01 Implants for surgery – Activ	e implantable medical devices – Part 3: Impla	antable n	eurostimu
Please answer the following questions		Yes	No
Is this standard recognized by FDA ² ?		×	
FDA Recognition number ³		# <u>17-10</u>	
Was a third party laboratory responsible for testing conformity in the 510(k)?		X	
Is a summary report ⁴ describing the extent of conformance of 510(k)? If no, complete a summary report table.		X	
Does the test data for this device demonstrate conformity to the pertains to this device?		X	
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X	
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	of tests?	X	
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA suppleme			
Were deviations or adaptations made beyond what is specifie If yes, report these deviations or adaptations in the summary			X
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			X
Is there an FDA guidance ⁶ that is associated with this standa If yes, was the guidance document followed in preparation of Title of guidance:			XX
 search.cfm 4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); 	 certification body involved in conformance assessme standard. The summary report includes information o utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is addition: which is necessary before FDA recognizes the stand http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfs search.cfm ⁶ The online search for CDRH Guidance Documents ca www.fda.gov/cdrh/guidance.html 	n all stand al informati ard. Found Standards/	ion d at

		ANDARD CONFORMANCE RY REPORT TABLE	
STANDARD TITLE AAMI/ANSI/ISO 14	708-3:2008-01-01 Implants for surger	y – Active implantable medical devices – Pa	urt 3: Implantable neurostim
	CONFORMANCE	WITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION C	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	ed under "justification." Some standard uately justified as appropriate for the s wing a standard is required under "type ne page may be necessary. can include an exclusion of a section i	ate whether conformance is met. If a section s include options, so similar to deviations, th ubject device. Explanation of all deviations o of deviation or option selected," "description n the standard, a deviation brought out by th to the device, or any adaptation of a section.	e option chosen needs to be r description of options " and "justification" on the e FDA supplemental
		Reduction Act Statement	
time for review completing and	ng burden for this collection of informativing instructions, searching existing data	ation is estimated to average 1 hour per resp ata sources, gathering and maintaining the da ion. Send comments regarding this burden es	ata needed, and
Food Office 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB cont	of information unless it

	Form Approved: OMB No. 0910-0120; Expi	ration Da	te: 12/31/13
Department of Health and Hu Food and Drug Admin STANDARDS DATA REPO (To be filled in by ap	nistration DRT FOR 510(k)s		
This report and the Summary Report Table are to be completed be ences a national or international standard. A separate report is req			
TYPE OF 510(K) SUBMISSION			
STANDARD TITLE ¹	Abbreviated		
AAMI/ANSI/ISO 14971:2007/(R) 2010 Medical devices - Application of	frisk 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 th in the 510(k)?			X
Is a summary report ⁴ describing the extent of conformance of the s 510(k)? If no, complete a summary report table.		×	
Does the test data for this device demonstrate conformity to the rec pertains to this device?		×	
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X	
Does this standard include more than one option or selection of tes If yes, report options selected in the summary report table.	sts?		X
Were there any deviations or adaptations made in the use of the st If yes, were deviations in accordance with the FDA supplemental ir			
Were deviations or adaptations made beyond what is specified in the lf yes, report these deviations or adaptations in the summary report			X
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			X
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 5 Title of guidance:			
[title of standard] [date of publication] stand ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html utilize ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/ ⁵ The s search.cfm * The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); * The or the options or a selection of methods are described;	ication body involved in conformance assessment dard. The summary report includes information on ed during the development of the device. supplemental information sheet (SIS) is additional h is necessary before FDA recognizes the standar //www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfSt ch.cfm online search for CDRH Guidance Documents car .fda.gov/cdrh/guidance.html	all standa informatio rd. Found tandards/	on at

		NDARD CONFORMANCE		
STANDARD TITLE AAMI/ANSI/ISO 14	4971:2007/(R) 2010 Medical devices - A	pplication of risk management to medical	devices	
	CONFORMANCE W	ITH 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	8 - 48 - 48 - 48 - 48 - 48 - 48 - 48 -	CONFORMANCE?	
TYPE OF DEVIATION (OR OPTION SELECTED *		Yes No N/A	
DECODUCTION				
DESCRIPTION				
JUSTIFICATION			s.	
 * 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. 				
	Paperwork Re	eduction Act Statement		
time for review completing an	wing instructions, searching existing data	on is estimated to average 1 hour per resp a sources, gathering and maintaining the d n. Send comments regarding this burden e sestions for reducing this burden to:	ata needed, and	
Food Offic 1350	artment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 cville, MD 20850	An agency may not conduct or spor required to respond to, a collection displays a currently valid OMB con	of information unless it	

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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)				
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced in the second standard standard.	510(k) t in the 51	hat refer- 10(k).		
TYPE OF 510(K) SUBMISSION				
STANDARD TITLE ¹ ISO 15223-1 Second Edition 2012-07-01 Medical devices - Symbols to be used with medical device labels, label	ing and i	nformatio		
Please answer the following questions	Yes	No		
Is this standard recognized by FDA ² ?	×			
FDA Recognition number ³	# <u>5-73</u>			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		X		
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.		X		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		X		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X		
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		X		
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.		X		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X		
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 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [citle 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 ⁵ The supplemental information sheet (SIS) is addition which is necessary before FDA recognizes the standard; requirements not applicable to the device; and the name and address of the test laboratory or 	on all stan nal informa dard. Fou fStandards	ntion nd at s/		

		NDARD CONFORMANCE Y REPORT TABLE	
STANDARD TITLE ISO 15223-1 Second	Edition 2012-07-01 Medical devices -	Symbols to be used with medical device la	bels, labeling and informatio
	CONFORMANCE W	ITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE	a na kala na kala kala kala kala kala ka	CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION C	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION C	OR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adeq selected when follow report. More than o	ed under "justification." Some standards uately justified as appropriate for the sub ving a standard is required under "type o ne page may be necessary.	te whether conformance is met. If a section include options, so similar to deviations, th oject device. Explanation of all deviations o f deviation or option selected," "description the standard, a deviation brought out by th	e option chosen needs to be r description of options " and "justification" on the
		the device, or any adaptation of a section.	
		eduction Act Statement	
time for review completing and	ving instructions, searching existing data	on is estimated to average 1 hour per resp a sources, gathering and maintaining the da a. Send comments regarding this burden est sections for reducing this burden to:	ata needed, and
Food Office 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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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 ES 60601-1:2005/(R) 2012 and C1:2009/(R)2012 Medical electrical equipment - Part 1-2: General	al requirem	ients for 🙀		
Please answer the following questions	Yes	No		
Is this standard recognized by FDA ² ?	×			
FDA Recognition number ³	# <u>2-156</u>			
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.	. X			
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 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 ⁵ The supplemental information sheet (SIS) is additionate 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 	on on all star itional informa andard. Fou s/cfStandard	ation nd at s/		

		RD CONFORMANCE		
STANDARD TITLE	01 1.2005/(7) 2012 1 01 2000/(7) 2012	adiant alastria ta anima da Davida). Cana-1	anto for 1
AAMI ANSI ES 606	01-1:2005/(R) 2012 and C1:2009/(R)2012 M		2: General requirem	ents for +
		STANDARD SECTIONS*	CONFORMANCE?	
SECTION NUMBER	SECTION TITLE			□ N/A
	ALL OR OPTION SELECTED *		K res ino	
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
8.9.3	Spaces filled by insulating compound		Yes No	✔ N/A
TIPE OF DEVIATION C				
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 C	R OPTION SELECTED *			
DESCRIPTION				
DESCRIPTION				
JUSTIFICATION				
ME Equipment does	not connect to Mains			
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	et all sections of the standard and indicate wh ad under "justification." Some standards include uately justified as appropriate for the subject of ving a standard is required under "type of dev ne page may be necessary. can include an exclusion of a section in the st IS), a deviation to adapt the standard to the o	le options, so similar to deviations, th device. Explanation of all deviations o iation or option selected," "description candard, a deviation brought out by th	e option chosen nee or description of option n" and "justification" ne FDA supplementa	eds to be ons on the
	Paperwork Reduct	ion Act Statement		
time for review completing and	ng burden for this collection of information is ving instructions, searching existing data sound d reviewing the collection of information. Ser collection of information, including suggestio	rces, gathering and maintaining the dand comments regarding this burden e	ata needed, and	
Food Offici 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless	

	EXTENT OF STANDARI SUMMARY REPO		
STANDARD TITLE	1 1.0005/(D) 2010 1 01.2000/(D) 2010 1 5		
AAMI ANSI ES 6060	1-1:2005/(R) 2012 and C1:2009/(R)2012 Medi		: General requirements for
	CONFORMANCE WITH STA	ANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
9.2 TYPE OF DEVIATION OF	Hazards associated with moving parts		Yes No X N/A
DESCRIPTION			
JUSTIFICATION			
ME Equipment does n	ot have moving parts		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
9.4	Instability hazards		Yes No 🕅 N/A
TYPE OF DEVIATION OF	ROPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			hanna ann an ann an Alban, a ca' Mhainnean a Shaanaan Ara
ME Equipment does n	ot have instability hazards		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
9.5	Expelled parts hazards		Yes No X N/A
TYPE OF DEVIATION OF	OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
ME Equipment does no	ot have expelled parts		
explanation is needed described and adequ selected when followi report. More than on	all sections of the standard and indicate whethe d under "justification." Some standards include o ately justified as appropriate for the subject devi ng a standard is required under "type of deviatio e page may be necessary.	options, so similar to deviations, the ice. Explanation of all deviations of on or option selected," "description	e option chosen needs to be r description of options " and "justification" on the
	an include an exclusion of a section in the stand S), a deviation to adapt the standard to the device		e FDA supplemental
	Paperwork Reduction	Act Statement	
time for reviewi completing and	burden for this collection of information is esti- ng instructions, searching existing data sources reviewing the collection of information. Send c llection of information, including suggestions f	, gathering and maintaining the da	ata needed, and
Food a Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer iccard Drive, Room 400 lle, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB cont	of information unless it

		NDARD CONFORMANCE Y REPORT TABLE		
STANDARD TITLE				
AAMI ANSI ES 60	601-1:2005/(R) 2012 and C1:2009/(R)20	12 Medical electrical equipment - Part 1-	2: General require	ements for 🛓
	CONFORMANCE W	ITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE	?
9.6	Acoustic energy and vibration		Yes N	lo 🕅 N/A
TTPE 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 pe	eumatic and hydraulic pressure		
TYPE OF DEVIATION O	DR OPTION SELECTED *			
	2			
DESCRIPTION				
JUSTIFICATION				
ME Equipment does	not have pressure			
SECTION NUMBER	SECTION TITLE		CONFORMANCE	?
9.8	Hazards associated with support system	18	Yes N	⊳ 🔀 N/A
TYPE OF DEVIATION C	R OPTION SELECTED *			
DECODIDITION				
DESCRIPTION				
JUSTIFICATION				1 martine and a second
ME Equipment does i	not have support system			
explanation is needed described and adeque selected when follow report. More than or * Types of deviations	et all sections of the standard and indicate ad under "justification." Some standards in uately justified as appropriate for the subje ving a standard is required under "type of ne page may be necessary. can include an exclusion of a section in th IS), a deviation to adapt the standard to th	Iclude options, so similar to deviations, the act device. Explanation of all deviations of deviation or option selected," "description ne standard, a deviation brought out by the	e option chosen n r description of op " and "justification	eeds to be tions " on the
	Paperwork Red	luction Act Statement		
completing and	g burden for this collection of information ring instructions, searching existing data a l reviewing the collection of information. collection of information, including suggest	sources, gathering and maintaining the da Send comments regarding this burden es	ta needed and	
Depar Food a Office 1350 I	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 tille, MD 20850	An agency may not conduct or spons required to respond to, a collection of displays a currently valid OMB conti	of information unles	not s it

	EXTENT OF STANDAR SUMMARY REI		
STANDARD TITLE			
AAMI ANSI ES 6060	01-1:2005/(R) 2012 and C1:2009/(R)2012 Me	dical electrical equipment - Part 1-2	2: General requirements for
	CONFORMANCE WITH ST	TANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
10.1-10.2 TYPE OF DEVIATION O	X-Radiation and Alpha, beta, gamma, neutr R OPTION SELECTED *	on and other particle radiation	Yes No X N//
DESCRIPTION			
JUSTIFICATION			
ME Equipment does r	not produce these types of radiation		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
10.4-10.7	Lasers, visible electromagnetic radiation, inf	rared, and ultraviolet	Yes No 🐼 N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
ME Equipment does n	ot produce these types of radiation		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
11.3-11.5	Fire enclosures of ME Equipment, use with f	lammable anesthetics, and use wit	Yes No 😿 N/A
TYPE OF DEVIATION OF	OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
ME Equipment not inte	ended to be used with flammable materials		
explanation is needed described and adequa selected when followi report. More than one	all sections of the standard and indicate wheth d under "justification." Some standards include ately justified as appropriate for the subject der ng a standard is required under "type of deviat e page may be necessary.	options, so similar to deviations, the vice. Explanation of all deviations of ion or option selected," "description	e option chosen needs to be description of options and "justification" on the
information sheet (SIS	an include an exclusion of a section in the star S), a deviation to adapt the standard to the dev	idard, a deviation brought out by the rice, or any adaptation of a section.	e FDA supplemental
	Paperwork Reduction	n Act Statement	
time for reviewi	burden for this collection of information is esing instructions, searching existing data source reviewing the collection of information. Send llection of information, including suggestions	es, gathering and maintaining the da comments regarding this burden es	ta needed, and
Food an Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer iccard Drive, Room 400 Ile, MD 20850	An agency may not conduct or spons required to respond to, a collection o displays a currently valid OMB cont	of information unless it

		NDARD CONFORMANCE Y REPORT TABLE		
STANDARD TITLE				
AAMI ANSI ES 6060	01-1:2005/(R) 2012 and C1:2009/(R)201	12 Medical electrical equipment - Part 1-2	2: General requireme	ents for 🛏
	CONFORMANCE W	ITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
11.7	Biocompatibility of ME Equipment		Yes No	☑ N/A
TYPE OF DEVIATION O	R OPTION SELECTED *		L	
DESCRIPTION				
JUSTIFICATION				
ME Equipment not int	tended to directly contact human tissue			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
11.8	Interruption of the power supply to MI	E Equipment	Yes No	N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
ME Equipment not co	nnected to mains			3
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
15.2	Serviceability		Yes No	N/A
TYPE OF DEVIATION OF	ROPTION SELECTED *			
DESCRIPTION				
ULOTIFICATION				
JUSTIFICATION	and add to be serviced			
ME Equipment not inte	ended to be serviced			
explanation is needed described and adequa selected when followi	d under "justification." Some standards ir ately justified as appropriate for the subj	e whether conformance is met. If a section include options, so similar to deviations, the ect device. Explanation of all deviations or deviation or option selected," "description	e option chosen nee description of optio	ds to be ns
* Types of deviations c information sheet (SIS	an include an exclusion of a section in the standard to t standard to t	ne standard, a deviation brought out by the he device, or any adaptation of a section.	e FDA supplemental	
	Paperwork Rec	luction Act Statement		
time for reviewi completing and	burden for this collection of information ng instructions, searching existing data	n is estimated to average 1 hour per response sources, gathering and maintaining the da Send comments regarding this burden es	ita needed, and	
Food a Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer iccard Drive, Room 400 lle, MD 20850	An agency may not conduct or spons required to respond to, a collection o displays a currently valid OMB cont	of information unless i	

		ANDARD CONFORMANCE RY REPORT TABLE			
STANDARD TITLE AAMI ANSI ES 60	601-1:2005/(R) 2012 and C1:2009/(R)2	012 Medical electrical equipment - Part 1-	2: General re	equirem	ents for]+
	CONFORMANCE	WITH STANDARD SECTIONS*			
SECTION NUMBER	SECTION TITLE		CONFORM	ANCE?	
15.4.3.4	Lithium batteries		X Yes	No No	🗌 N/A
	OR OPTION SELECTED *		-1		
ME Equipment's lith	nium battery is not tested to IEC 60086-	4 or 62133. The battery is instead certified	1 UL1642		
DESCRIPTION					
JUSTIFICATION					
The battery is a sing	le cell secondary battery with regulator	and Qi charging compliant. UL1642 certif	ication mitig	ates the	risks.
SECTION NUMBER	SECTION TITLE		CONFORM		
15.5	Mains Supply Transformers			No	🗙 N/A
TYPE OF DEVIATION	OR OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION	· · · · · · · · · · · · · · · · · · ·				
ME Equipment not c	connected to mains				
SECTION NUMBER	SECTION TITLE		1		
16.4-16.5			CONFORM	Contractor and	
	Enclosures, Separation Devices		Yes	No	🔀 N/A
DESCRIPTION					
DEGORITHON					
JUSTIFICATION		-			
	ade with electronics ME Equipment do	es not have maintenance, calibration or ren	1.6		
	ace white electronices, the Equipment do	es not have mannenance, calibration or ren	ioval of curr	ents.	
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	ed under "justification." Some standards uately justified as appropriate for the su wing a standard is required under "type on ne page may be necessary. can include an exclusion of a section in	te whether conformance is met. If a section include options, so similar to deviations, th bject device. Explanation of all deviations of of deviation or option selected," "description the standard, a deviation brought out by the	e option cho r description n" and "justifi e FDA suppl	sen nee of optio cation" c	ds to be ns on the
information sheet (C	sis), a deviation to adapt the standard to	the device, or any adaptation of a section.			
		eduction Act Statement			
time for review completing and	ving instructions, searching existing dat	ion is estimated to average 1 hour per resp a sources, gathering and maintaining the da n. Send comments regarding this burden es gestions for reducing this burden to:	ata needed, a	ind	
Food Office	rtment of Health and Human Services and Drug Administration e of Chief Information Officer	An agency may not conduct or spon			
	Piccard Drive, Room 400 ville, MD 20850	required to respond to, a collection displays a currently valid OMB con		ı unless i	t
RM FDA 3654 (12/1	0)	Page 2		No. of Concession, Name	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	EXTENT OF STANDAR SUMMARY REP		
STANDARD TITLE			
AAMI ANSI ES 6060	01-1:2005/(R) 2012 and C1:2009/(R)2012 Med	lical electrical equipment - Part 1-2	2: General requirements for ∓
	CONFORMANCE WITH ST	ANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
16.9	ME System connections and wiring		Yes No XN/A
TYPE OF DEVIATION OF	R OPTION SELECTED *		а.,
DESCRIPTION			
JUSTIFICATION			
ME Equipment wiring	and connections not accessible by user or tech	unician. Incorrect connections can	not be made.
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *		
DESCRIPTION			1
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION OF	ROPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adequa selected when followi report. More than one	all sections of the standard and indicate wheth d under "justification." Some standards include ately justified as appropriate for the subject dev ng a standard is required under "type of deviati e page may be necessary. an include an exclusion of a section in the stan	options, so similar to deviations, th vice. Explanation of all deviations o ion or option selected," "description	e option chosen needs to be r description of options " and "justification" on the
	S), a deviation to adapt the standard to the dev		
	Paperwork Reduction		
time for reviewi completing and	burden for this collection of information is es ng instructions, searching existing data source reviewing the collection of information. Send llection of information, including suggestions	s, gathering and maintaining the da comments regarding this burden es	ata needed, and
Food a Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer iccard Drive, Room 400 Ille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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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)				
This report and the Summary Report Table are to be completed by the applicant when submitting ences a national or international standard. A separate report is required for each standard reference	a 510(k) d in the 5	that refer- 10(k).		
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 safe	ety and ess	ential perfe		
Please answer the following questions	Yes	No		
Is this standard recognized by FDA ² ?	. 🗴			
FDA Recognition number ³	. # <u>5-54</u>			
Was a third party laboratory responsible for testing conformity of the device to this standard identifie in the 510(k)?	d X			
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:	Lange of the second sec			
 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 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [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 ⁵ The supplemental information sheet (SIS) is addited which is necessary before FDA recognizes the state http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search.cfm ⁶ The online search for CDRH Guidance Document www.fda.gov/cdrh/guidance.html 	n on all stand onal informat ndard. Foun /cfStandards	ion d at		

	EXTENT OF STANDA SUMMARY RE	RD CONFORMANCE			
STANDARD TITLE AAMI ANSI IEC 60	0601-1-2:2007 Medical electrical equipment -	Part 1-2: General requirements for t	pasic safety and	d esser	ntial perf
	CONFORMANCE WITH S	STANDARD SECTIONS*			
SECTION NUMBER	SECTION TITLE		CONFORMAN	NCE?	
All	All		Yes	No	🗌 N/A
TYPE OF DEVIATION	DR OPTION SELECTED *				
DESCRIPTION					Ŧ
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE		CONFORMAN	NCE?	
6.1.3	Protection of other equipment from low-free	quency magnetic fields	Yes] No	N/A
TYPE OF DEVIATION (DR OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
ME Equipment is no	t connected to Mains line				
SECTION NUMBER	SECTION TITLE		CONFORMAN	NCE?	
6.2.5	Surges		Yes [No	N/A
TYPE OF DEVIATION C	OR OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
ME Equipment is inte	ernally powered, not connected to Mains line				
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	at all sections of the standard and indicate whe ad under "justification." Some standards includ uately justified as appropriate for the subject d ving a standard is required under "type of devi ne page may be necessary. can include an exclusion of a section in the sta	e options, so similar to deviations, th evice. Explanation of all deviations o ation or option selected," "description andard, a deviation brought out by th	ne option chose or description o n" and "justifica ne FDA suppler	en nee of option ation" o	ds to be ns n the
Information sheet (S	IS), a deviation to adapt the standard to the d	evice, or any adaptation of a section.			
	Paperwork Reducti				
time for review completing and	g burden for this collection of information is ving instructions, searching existing data sour- l reviewing the collection of information. Sen ollection of information, including suggestion	ces, gathering and maintaining the d d comments regarding this burden e	ata needed, and	d	
Food Office 1350	tment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 rille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information u		

	EXTENT OF STANDARD SUMMARY REPO			
STANDARD TITLE	01 1 2:2007 Modical classical and Date	1.2.0		
AAMI ANSI IEC 600	01-1-2:2007 Medical electrical equipment - Part		isic safety and esse	ential pert
SECTION NUMBER	CONFORMANCE WITH STAN	NDARD SECTIONS*	CONFORMANCE?	
6.2.7	Voltage dips, short interruptions, and voltage v	ariations on power sully input L		N/A
TYPE OF DEVIATION O	R OPTION SELECTED *	and the surface of th		
DESCRIPTION				Ŧ
JUSTIFICATION				
ME Equipment is not	connected to Mains line			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION OF			Yes No	□ N/A
TYPE OF DEVIATION O	ROPTION SELECTED *			
DESCRIPTION				
JUSTIFICATION				
SECTION NUMBER	SECTION TITLE		CONFORMANCE?	
TYPE OF DEVIATION OF	OPTION SELECTED *		Yes No	□ N/A
DESCRIPTION				
JUSTIFICATION				
explanation is needed described and adequa selected when followi	all sections of the standard and indicate whether d under "justification." Some standards include op ately justified as appropriate for the subject device ng a standard is required under "type of deviation e page may be necessary.	tions, so similar to deviations, the e. Explanation of all deviations or	option chosen need description of option	eds to be ons
* Types of deviations c information sheet (SI	an include an exclusion of a section in the standa S), a deviation to adapt the standard to the device	rd, a deviation brought out by the , or any adaptation of a section.	FDA supplementa	ıl
	Paperwork Reduction A	ct Statement		
time for reviewi completing and	burden for this collection of information is estim ng instructions, searching existing data sources, g reviewing the collection of information. Send con llection of information, including suggestions for	gathering and maintaining the data mments regarding this burden est	ta needed, and	
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	approved.	01010110	. 0010-0120,	LApitation	Date. 12/01/10

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 IEC 60601-1-11 Edition 1.0:2010 Medical electrical equipment – Part 1-11: General requirements for basic safet	y and es:	sential perf		
Please answer the following questions	Yes	No		
Is this standard recognized by FDA ² ?	X			
FDA Recognition number ³	# <u>5-58</u>			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		X		
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.	X			
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?	X			
Title of guidance: Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for	Home U	Jse		
 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 ⁶ The online search for CDRH Guidance Documents can www.fda.gov/cdrh/guidance.html 	n all stand al informat ard. Found Standards/	ion d at		

		ANDARD CONFORMANCE	
STANDARD TITLE IEC 60601-1-11 Ed	ition 1.0:2010 Medical electrical equipr	nent – Part 1-11: General requirements fo	r basic safety and essential per
		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?
TYPE OF DEVIATION			Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION (DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
explanation is need described and adeq selected when follow report. More than o * Types of deviations	ed under "justification." Some standards uately justified as appropriate for the su wing a standard is required under "type ne page may be necessary. can include an exclusion of a section in	ate whether conformance is met. If a sections include options, so similar to deviations, to bject device. Explanation of all deviations of deviation or option selected," "description the standard, a deviation brought out by to bothe device, or any adaptation of a section	the option chosen needs to be or description of options on" and "justification" on the the FDA supplemental
	Paperwork R	eduction Act Statement	
time for review completing and	ng burden for this collection of informat ving instructions, searching existing dat	tion is estimated to average 1 hour per resp ta sources, gathering and maintaining the open. Send comments regarding this burden of	data needed, and
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Page 2

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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)					
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced					
TYPE OF 510(K) SUBMISSION					
STANDARD TITLE ¹ IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Ele	ectrostati	e discharg			
Please answer the following questions	Yes	No			
Is this standard recognized by FDA ² ?		\boxtimes			
FDA Recognition number ³	#Not Ap	plicable			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	\boxtimes				
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.	\boxtimes				
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\times				
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\times				
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes			
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 ?		\boxtimes			
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.		\boxtimes			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		\boxtimes			
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 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 ^a 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 	ludes inforr evice. Il informatic und at http ards/search an be found	mation on on which :// .cfm Tat			

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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 WIT	H STANDARD SECTIONS*				
SECTION NUMBER ALL	SECTION TITLE ALL	ny any any any any and a desire set of the set		ANCE?	□ N/A	
TYPE OF DEVIATION O	R OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION		-				
SECTION NUMBER	SECTION TITLE			ANCE?		
TYPE OF DEVIATION O	R OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE	-		ANCE?	□ N/A	
DESCRIPTION						
JUSTIFICATION				ménet keléskenetiketetete		
 * 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 						
mormation sheet (Sh	S), a deviation to adapt the standard to the					
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour 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:						
Department of Health and Human ServicesFood and Drug AdministrationOffice of Chief Information Officer1350 Piccard Drive, Room 400Rockville, MD 20850						

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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)					
This report and the Summary Report Table are to be comp ences a national or international standard. A separate repor					
TYPE OF 510(K) SUBMISSION Traditional STANDARD TITLE ¹ IEC 61000-4-8:2009 Electromagnetic compatibility (EMC) – Part 4	Abbreviated				
Please answer the following questions	4-8. Testing and measurement techniques – Po	Yes	No		
Is this standard recognized by FDA ² ?			\boxtimes		
FDA Recognition number ³		#Not Ap	plicable		
Was a third party laboratory responsible for testing conformi in the 510(k)?		\boxtimes			
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.		\boxtimes			
Does the test data for this device demonstrate conformity to pertains to this device?		\times			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\times			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	n of tests?		\boxtimes		
Were there any deviations or adaptations made in the use o If yes, were deviations in accordance with the FDA supplem			\square		
Were deviations or adaptations made beyond what is specif If yes, report these deviations or adaptations in the summary			\boxtimes		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes		
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation o 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 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 inva assessment to this standard. The summary report inc all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. Fo www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda 6 The online search for CDRH Guidance Documents ca http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	ludes infor evice. Il information und at http unds/search in be found	mation on on which ::// n.cfm I at		

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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 S	STANDARD SECTIONS*			
SECTION NUMBER ALL	SECTION TITLE ALL		CONFORMANCE?		
TYPE OF DEVIATION OF	R OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE		CONFORMANCE?		
TYPE OF DEVIATION OF	R OPTION SELECTED *		1		
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE		CONFORMANCE?		
TYPE OF DEVIATION OF	R 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.					
	Paperwork Reduct	ion Act Statement			
Public reporting burden for this collection of information is estimated to average 1 hour 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:					
Department of Health and Human ServicesFood and Drug AdministrationOffice of Chief Information Officer1350 Piccard Drive, Room 400Rockville, MD 20850					

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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)					
This report and the Summary Report Table are to be comp ences a national or international standard. A separate report	pleted by the applicant when submitting a rt is required for each standard referenced	510(k) t in the 5	hat refer- 10(k).		
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 – Ra	diated, ra	adio-frequ		
Please answer the following questions		Yes	No		
Is this standard recognized by FDA ² ?			\boxtimes		
FDA Recognition number ³		#Not Ap	plicable		
Was a third party laboratory responsible for testing conform in the 510(k)?		\times			
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.		\boxtimes			
Does the test data for this device demonstrate conformity to pertains to this device?		\times			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\boxtimes			
Does this standard include more than one option or selectio If yes, report options selected in the summary report table.	n of tests?		\boxtimes		
Were there any deviations or adaptations made in the use of			\boxtimes		
If yes, were deviations in accordance with the FDA supplem	nental information sheet (SIS) ⁵ ?				
Were deviations or adaptations made beyond what is specifing the specific or adaptations in the summar of the summar set of the se			\boxtimes		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes		
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation of 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 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 invo assessment to this standard. The summary report incl all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. Fo www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStanda 6 The online search for CDRH Guidance Documents ca http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	ludes infor evice. Il information und at http ards/search in be found	mation on on which ::// n.cfm t at		

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		DARD CONFORMANCE REPORT TABLE	
STANDARD TITLE IEC 61000-4-3:2010 E	Electromagnetic compatibility (EMC) – P	art 4-3: Testing and measurement techni	iques – Radiated, radio-frequ
	CONFORMANCE WIT	H STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE ALL		CONFORMANCE?
TYPE OF DEVIATION OF	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION OF	ROPTION SELECTED *		-
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION OF	ROPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adequ selected when followi report. More than on * Types of deviations o	all sections of the standard and indicate d under "justification." Some standards in ately justified as appropriate for the subje ing a standard is required under "type of o e page may be necessary. an include an exclusion of a section in th S), a deviation to adapt the standard to th	clude options, so similar to deviations, th ct device. Explanation of all deviations o deviation or option selected," "description e standard, a deviation brought out by th	e option chosen needs to be r description of options " and "justification" on the e FDA supplemental
		uction Act Statement	
time for review completing and	g burden for this collection of information ing instructions, searching existing data s reviewing the collection of information. Illection of information, including sugges	n is estimated to average 1 hour per responences, gathering and maintaining the data Send comments regarding this burden estimates and the send comments regarding the sen	ata needed, and
Food a Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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 comple ences a national or international standard. A separate report i	eted by the applicant when submitting a t is required for each standard referenced i	510(k) th n the 51	nat refer- 0(k).		
TYPE OF 510(K) SUBMISSION	Abbreviated				
STANDARD TITLE ¹ CISPR 11 ED. 5.1 B:2010 Industrial, scientific and medical equipme	ent – Radio-frequency disturbance characteris	tics – Lii	mits and		
Please answer the following questions		Yes	No		
Is this standard recognized by FDA 2?			\boxtimes		
FDA Recognition number ³		#Not Ap	plicable		
Was a third party laboratory responsible for testing conformit in the 510(k)?	y of the device to this standard identified	\boxtimes			
Is a summary report ⁴ describing the extent of conformance of 510(k)? If no, complete a summary report table.	of the standard used included in the	\boxtimes			
Does the test data for this device demonstrate conformity to pertains to this device?	the requirements of this standard as it	\boxtimes			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\boxtimes			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	ו of tests?		\boxtimes		
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA supplem	f the standard? ental information sheet (SIS) ⁵ ?		\boxtimes		
Were deviations or adaptations made beyond what is specified of the second second what is specified of the second	ied in the FDA SIS? y report table.		\boxtimes		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes		
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:	of this 510K?				
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4 The summary report should include, any adaptations during data and a 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	6 The online search to CDKM collaboration booms with http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	onandGuid	ance/		

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		DARD CONFORMANCE REPORT TABLE			
STANDARD TITLE CISPR 11 ED. 5.1 B:	2010 Industrial, scientific and medical equ	ipment – Radio-frequency disturbance	characteristi	cs – Lim	uits and
	CONFORMANCE WIT	H STANDARD SECTIONS*			
SECTION NUMBER	SECTION TITLE ALL			ANCE?	□ N/A
TYPE OF DEVIATION C	R OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	N/A
TYPE OF DEVIATION C	R OPTION SELECTED *				
DESCRIPTION		×			
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	🗌 N/A
TYPE OF DEVIATION C	R OPTION SELECTED *		1		
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JUSTIFICATION					
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		ANNO 2010 AND ANNO 2010 ANNO 2010 ANNO 2010 ANNO 2010 ANNO 2010			
time for review completing and	Paperwork Redu g burden for this collection of information ving instructions, searching existing data so l reviewing the collection of information. So ollection of information, including suggest	ources, gathering and maintaining the da Send comments regarding this burden e	ata needed, a	and	
Food Office 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information		

FORM FDA 3654 (6/11)

Form	Approved ²	OMB No	0910-0120-	Expiration	Date: 12/31/13	
1 01111	Approved.	CIVID NO.	0310-0120,	LApitation	Date. 12/01/10	

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 com ences a national or international standard. A separate repo	npleted by the applicant when submitting a ort is required for each standard referenced	510(k) 1 in the 5	that refer- 10(k).		
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 electromag	netic fie	lds, 3kHz t		
Please answer the following questions		Yes	No		
Is this standard recognized by FDA 2?			\times		
FDA Recognition number ³		# Not Ap	plicable		
Was a third party laboratory responsible for testing conform in the 510(k)?	nity of the device to this standard identified	\boxtimes			
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.		\boxtimes			
Does the test data for this device demonstrate conformity to pertains to this device?		\times			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X			
Does this standard include more than one option or selection If yes, report options selected in the summary report table.			\boxtimes		
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA suppler					
Were deviations or adaptations made beyond what is speci If yes, report these deviations or adaptations in the summar			\boxtimes		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes		
Is there an FDA guidance ⁶ that is associated with this stand If yes, was the guidance document followed in preparation of 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 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 invo assessment to this standard. The summary report incl all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. Fou www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandar 6 The online search for CDRH Guidance Documents can http://www.fda.gov/MedicalDevices/DeviceRegulationa GuidanceDocuments/default.htm	udes inforr vice. I informatio Ind at http rds/search n be found	mation on on which :// .cfm at		

FORM FDA 3654 (6/11)

		NDARD CONFORMANCE Y REPORT TABLE	
STANDARD TITLE ANSI/IEEE C95.1-19	992 Standard for safety levels with respe	ect to human exposure to radio frequency	electromagnetic fields, 3kHz t
	CONFORMANCEW	ITH STANDARD SECTIONS*	
SECTION NUMBER ALL	SECTION TITLE ALL		CONFORMANCE?
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			~
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is neede described and adequ selected when follow	ed under "justification." Some standards i uately justified as appropriate for the sub	e whether conformance is met. If a section nclude options, so similar to deviations, th ject device. Explanation of all deviations o deviation or option selected," "description	e option chosen needs to be r description of options
* Types of deviations information sheet (S	can include an exclusion of a section in t IS), a deviation to adapt the standard to t	he standard, a deviation brought out by th the device, or any adaptation of a section.	e FDA supplemental
	Paperwork Re	duction Act Statement	
time for review completing and	ring instructions, searching existing data	on is estimated to average 1 hour per response sources, gathering and maintaining the date. Send comments regarding this burden est estions for reducing this burden to:	ata needed, and
Food a Office 1350 I	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB cont	of information unless it

Form Approved: OMB No.	0910-0120;	Expiration	Date:	12/31/13
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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)					
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) t in the 5	hat refer- 10(k)			
TYPE OF 510(K) SUBMISSION					
STANDARD TITLE ¹ IEEE 1528-2003 Recommended practice for determining the peak spatial average specific absorption rate (SAR)	in the hu	man head			
Please answer the following questions	Yes	No			
Is this standard recognized by FDA ² ?		\boxtimes			
FDA Recognition number ³	#Not Ap	plicable			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	\times				
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.	\boxtimes				
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\boxtimes				
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes				
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes			
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.		\boxtimes			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		\boxtimes			
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 ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.ofm 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 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standards of the test laboratory or certification body in assessment to this standard. The summary report in all standards utilized during the development of the standard. If a gov/scripts/cdrh/cfdocs/cfStandards/search.ofm 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 	icludes info device. nal informa Found at hi dards/seal can be fou	tion which tp:// ch.cfm nd at			

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		DARD CONFORMANCE			
STANDARD TITLE IEEE 1528-2003 Reco	ommended practice for determining the pea		rate (SAR) in	n the hur	nan head
	CONFORMANCE WITH	STANDARD SECTIONS*			
SECTION NUMBER ALL	SECTION TITLE ALL			ANCE?	□ N/A
TYPE OF DEVIATION O	R OPTION SELECTED *				
DESCRIPTION					98-166 an 166 act
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	□ N/A
TYPE OF DEVIATION OF	OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	□ N/A
TYPE OF DEVIATION OF	ROPTION SELECTED *				
DESCRIPTION	Y				
JUSTIFICATION					
explanation is needed described and adequa selected when followin report. More than one	all sections of the standard and indicate wi I under "justification." Some standards inclu ately justified as appropriate for the subject ng a standard is required under "type of de a page may be necessary. an include an exclusion of a section in the s	ude options, so similar to deviations, the device. Explanation of all deviations of viation or option selected," "description	e option cho r description " and "justific	sen need of option cation" o	ds to be ns n the
information sheet (SIS	a deviation to adapt the standard to the	device, or any adaptation of a section.	e r DA suppi	ementai	
time for reviewin completing and n	Paperwork Reduct burden for this collection of information is ng instructions, searching existing data sour reviewing the collection of information. Se llection of information, including suggestion	arces, gathering and maintaining the da and comments regarding this burden es	ita needed, a	nd	
Food ar Office o 1350 Pi	nent of Health and Human Services nd Drug Administration of Chief Information Officer ccard Drive, Room 400 lle, MD 20850	An agency may not conduct or spons required to respond to, a collection o displays a currently valid OMB cont	of information	son is noi 1 unless it	t.

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-	-2017	
Form Approved: OMB No. 0910-0120; Ex	piration Da	ate: 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 ences a national or international standard. A separate report is required for each standard referenced		
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 commu	nication	devices –
Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?		\boxtimes
FDA Recognition number ³	#Not Ap	plicable
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	\boxtimes	
Is a summary report ⁴ describing the extent of conformance of the standard used included in the		

In the 510(K)?		X		
	extent of conformance of the standard used included in the object of the standard used included used in the object of the standard used included used in the object of the standard used included used in the object of the standard used included used used in the object of the standard used used used used used used used use			
	est data for this device demonstrate conformity to the requirements of this standard as it this device?			
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\boxtimes		
	Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.			
	re any deviations or adaptations made in the use of the standard? ere 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 star If yes, was the guidance document followed in preparation Title of guidance:		Concession of the local division of the loca		
 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 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 inv assessment to this standard. The summary report inc all standards utilized during the development of the de 5 The supplemental information sheet (SIS) is additional is necessary before FDA recognizes the standard. Fo www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandard 6 The online search for CDRH Guidance Documents ca http://www.fda.gov/MedicalDevices/DeviceRegulation GuidanceDocuments/default.htm	ludes infor evice. al informati und at http ards/searcl an be found	mation on on which n:// n.cfm d at	
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		NDARD CONFORMANCE Y REPORT TABLE	
STANDARD TITLE IEC 62209-2:2010 H		from hand-held and body mounted wirel	ess communication devices –
		ITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL TYPE OF DEVIATION C	ALL DR OPTION SELECTED *		Yes No N/A
n pena di kalandari sitisiti katalandari di			
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	R OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
described and adeque selected when follow report. More than on	a under "justification." Some standards in lately justified as appropriate for the subje ing a standard is required under "type of le page may be necessary.	whether conformance is met. If a section clude options, so similar to deviations, the ect device. Explanation of all deviations of deviation or option selected," "description	e option chosen needs to be r description of options " and "justification" on the
* Types of deviations of information sheet (SI	can include an exclusion of a section in th S), a deviation to adapt the standard to the	e standard, a deviation brought out by the ne device, or any adaptation of a section.	e FDA supplemental
	Paperwork Red	uction Act Statement	
time for reviews	ing instructions, searching existing data s	n is estimated to average 1 hour per response sources, gathering and maintaining the da Send comments regarding this burden es stions for reducing this burden to:	ta needed and
Food a Office 1350 P	ment of Health and Human Services nd Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spons required to respond to, a collection of displays a currently valid OMB cont	of information unless it

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	Form Approved: OMB No. 0910-0120; Exp	oiration Da	ate: 12/31/13
Department of Health and Hu Food and Drug Admini STANDARDS DATA REPO (To be filled in by ap	stration RT FOR 510(k)s		
This report and the Summary Report Table are to be completed b ences a national or international standard. A separate report is requ			
TYPE OF 510(K) SUBMISSION			
Traditional Special A	bbreviated		
STANDARD TITLE ¹ GTRI E3 Test Protocol v5.1 2007 Test protocol for medical devices to secu	rity and logistical systems		
Please answer the following questions		Yes	No
Is this standard recognized by FDA 2?			\boxtimes
FDA Recognition number ³	#	₄Not Ap	plicable
Was a third party laboratory responsible for testing conformity of the in the 510(k)?		\boxtimes	
Is a summary report ⁴ describing the extent of conformance of the s 510(k)? If no, complete a summary report table.		\boxtimes	
Does the test data for this device demonstrate conformity to the req pertains to this device?		\times	
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		\boxtimes	
Does this standard include more than one option or selection of test If yes, report options selected in the summary report table.	s?		\boxtimes
Were there any deviations or adaptations made in the use of the sta If yes, were deviations in accordance with the FDA supplemental in			
Were deviations or adaptations made beyond what is specified in the If yes, report these deviations or adaptations in the summary report			\boxtimes
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			\boxtimes
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 57 Title of guidance:			
standard] [date of publication] assess ² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Standards/default.htm ⁵ The sup 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 mathe whon a patience of mothod a gra described, dwidtions from the standard (for example, alternative test methods); choices mathe assess all standards/ ⁵ The sup is necessively (for example, alternative test methods); choices mathe ⁶ The only http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	s of the test laboratory or certification body invo ment to this standard. The summary report incli- dards utilized during the development of the de oplemental information sheet (SIS) is additional assary before FDA recognizes the standard. Fou ccessdata.fda.gov/scripts/cdrh/cfdocs/cfStandar ine search for CDRH Guidance Documents car ww.fda.gov/MedicalDevices/DeviceRegulational ceDocuments/default.htm	udes inforr vice. I informatio und at http rds/search n be found	mation on on which :// u.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE					
STANDARD TITLE GTRI E3 Test Protoco	l v5.1 2007 Test protocol for medical dev	vices to security and logistical systems			
	CONFORMANCE WIT	H STANDARD SECTIONS*			
SECTION NUMBER ALL	SECTION TITLE ALL			IANCE?	□ N/A
TYPE OF DEVIATION OF	I R OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	[] N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *				
DESCRIPTION					
JUSTIFICATION					
SECTION NUMBER	SECTION TITLE			ANCE?	□ N/A
TYPE OF DEVIATION OF	ROPTION SELECTED *				
DESCRIPTION				****	
JUSTIFICATION					
explanation is needed described and adequ selected when following report. More than on * Types of deviations of	all sections of the standard and indicate d under "justification." Some standards ind ately justified as appropriate for the subje ing a standard is required under "type of c e page may be necessary. an include an exclusion of a section in the S), a deviation to adapt the standard to th	clude options, so similar to deviations, the ct device. Explanation of all deviations of leviation or option selected," "description e standard, a deviation brought out by the	e option cho r description " and "justif	osen nee n of optio ication" o	eds to be ons on the
	Paperwork Red	uction Act Statement			
time for review completing and	g burden for this collection of information ing instructions, searching existing data s reviewing the collection of information. Information, including sugges	ources, gathering and maintaining the da Send comments regarding this burden es	ata needed,	and	
Food a Office 1350 P	ment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spons required to respond to, a collection displays a currently valid OMB cont	of informatic		

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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)					
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) 1 in the 5	hat refer- 10(k).			
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)?		X			
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.	X				
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 ?		∑ X			
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.		X			
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?	X				
Title of guidance: Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Appli	cations				
 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 ⁶ The online search for CDRH Guidance Documents can www.fda.gov/cdrh/guidance.html 	n all standa al informatio ard. Found Standards/	on at			

		DARD CONFORMANCE REPORT TABLE	
STANDARD TITLE AAMI ANSI IEC 62	304:2006 Medical device software - Softwa	are life-cycle processes	
	CONFORMANCE WITH	STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION C	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE	*******	CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	at all sections of the standard and indicate we ad under "justification." Some standards incl uately justified as appropriate for the subject ving a standard is required under "type of de ne page may be necessary. can include an exclusion of a section in the IS), a deviation to adapt the standard to the	ude options, so similar to deviations, th t device. Explanation of all deviations o eviation or option selected," "description standard, a deviation brought out by th	e option chosen needs to be or description of options " and "justification" on the e FDA supplemental
	Paperwork Redu	ction Act Statement	
time for review completing and	g burden for this collection of information ving instructions, searching existing data so I reviewing the collection of information. S ollection of information, including suggest	is estimated to average 1 hour per resp purces, gathering and maintaining the d bend comments regarding this burden e	ata needed, and
Food Office 1350	tment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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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)	-	
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) in the 5	that refer- 10(k).
TYPE OF 510(K) SUBMISSION		
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)?		X
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.	X	
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.		X
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	X	
Title of guidance: Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factoria	tors and	Usa+
 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [itile 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 ² Certification body involved in conformance assessment standard. The summary report includes information outilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional which is necessary before FDA recognizes the standar http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfS search.cfm ⁶ The online search for CDRH Guidance Documents can www.fda.gov/cdrh/guidance.html 	nt to this n all stand al informati ard. Found Standards/	ards ion d at

		NDARD CONFORMANCE Y REPORT TABLE	
STANDARD TITLE			
AAMI ANSI IEC 62	2366:2007 Medical devices - Application	of usability engineering to medical devic	es
		ITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL OR OPTION SELECTED *		Yes No N/A
TTPE OF DEVIATION	SK OF HON SELECTED		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION (OR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION	1		
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
SECTION NOMBER			
TYPE OF DEVIATION	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is need described and adec selected when follo report. More than c * Types of deviations	led under "justification." Some standards i quately justified as appropriate for the sub wing a standard is required under "type of one page may be necessary. a can include an exclusion of a section in t	e whether conformance is met. If a section include options, so similar to deviations, the ject device. Explanation of all deviations of f deviation or option selected," "description the standard, a deviation brought out by the the device, or any adaptation of a section	ne option chosen needs to be or description of options n" and "justification" on the ne FDA supplemental
Dati	•	duction Act Statement	including the
time for review completing an	wing instructions, searching existing data	on is estimated to average 1 hour per resp a sources, gathering and maintaining the d a. Send comments regarding this burden e estions for reducing this burden to:	ata needed, and
Food Offic 1350	artment of Health and Human Services and Drug Administration be of Chief Information Officer Piccard Drive, Room 400 aville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

Form	Annroved.	OMR No.	0910-0120;	Evniration	Data:	12/21/12
1 01111	Approved.	CIVID NO.	0310-0120,	LApiration	Date.	12/01/10

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 comple ences a national or international standard. A separate report is	eted by the applicant when submitting a s required for each standard referenced	510(k) t in the 5	hat refer- 10(k).		
TYPE OF 510(K) SUBMISSION					
Traditional Special	Abbreviated				
STANDARD TITLE ¹ BS EN 556-1:2001 Sterilization of medical devices - Requirements f	for medical devices to be designated "STERI	LE" – Pa	art1: Requi		
Please answer the following questions		Yes	No		
Is this standard recognized by FDA ² ?			X		
FDA Recognition number ³		¥ Not Ap	oplicable		
Was a third party laboratory responsible for testing conformity in the 510(k)?			X		
Is a summary report ⁴ describing the extent of conformance of 510(k)? If no, complete a summary report table.		X			
Does the test data for this device demonstrate conformity to the 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 If yes, report options selected in the summary report table.	of tests?	X			
Were there any deviations or adaptations made in the use of the line of the li					
Were deviations or adaptations made beyond what is specified If yes, report these deviations or adaptations in the summary r			X		
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 standar If yes, was the guidance document followed in preparation of t Title of guidance:					
 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; 	certification body involved in conformance assessment standard. The summary report includes information of utilized during the development of the device. The supplemental information sheet (SIS) is additional which is necessary before FDA recognizes the standa http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfS search.cfm The online search for CDRH Guidance Documents ca www.fda.gov/cdrh/guidance.html	n all stand al informati ard. Found Standards/	ion d at		

		DARD CONFORMANCE REPORT TABLE	
STANDARD TITLE BS EN 556-1:2001 S	Sterilization of medical devices - Requirem	ents for medical devices to be designate	ed "STERILE" – Partl: Requi
	CONFORMANCE WIT	H STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION (DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION (DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
explanation is need described and adeq selected when follow report. More than o * Types of deviations	st all sections of the standard and indicate ve ed under "justification." Some standards inc uately justified as appropriate for the subjec- wing a standard is required under "type of d ne page may be necessary. can include an exclusion of a section in the SIS), a deviation to adapt the standard to the	elude options, so similar to deviations, the ct device. Explanation of all deviations of eviation or option selected," "description estandard, a deviation brought out by the	e option chosen needs to be in description of options n" and "justification" on the ne FDA supplemental
time for review completing an	Paperwork Redu ng burden for this collection of information wing instructions, searching existing data so d reviewing the collection of information. S collection of information, including sugges	ources, gathering and maintaining the d Send comments regarding this burden e	ata needed, and
Food Offic 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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 comp ences a national or international standard. A separate repor	pleted by the applicant when submitting a t is required for each standard referenced	510(k) 1 in the 5	that refer- 10(k).		
TYPE OF 510(K) SUBMISSION					
Traditional Special	Abbreviated				
STANDARD TITLE ¹ EN 1041:2008 Information supplied by the manufacturer of medic	al devices				
Please answer the following questions		Yes	No		
Is this standard recognized by FDA ² ?			×		
FDA Recognition number ³		# Not Ap	oplicable		
Was a third party laboratory responsible for testing conforminin the 510(k)?	ty of the device to this standard identified		X		
Is a summary report ⁴ describing the extent of conformance 510(k)? If no, complete a summary report table.	X				
Does the test data for this device demonstrate conformity to pertains to this device?	the requirements of this standard as it	×			
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 If yes, report options selected in the summary report table.	n of tests?	X			
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA suppleme					
Were deviations or adaptations made beyond what is specifi If yes, report these deviations or adaptations in the summary	ed in the FDA SIS? report table.		×		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			X		
Is there an FDA guidance ⁶ that is associated with this standa If yes, was the guidance document followed in preparation of 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 assessme standard. The summary report includes information or utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is addition which is necessary before FDA recognizes the stand http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf search.cfm ⁶ The online search for CDRH Guidance Documents co www.fda.gov/cdrh/guidance.html	on all stand al informati ard. Found Standards/	on Lat		

		ANDARD CONFORMANCE RY REPORT TABLE	
STANDARD TITLE			
EN 1041:2008 Infor	mation supplied by the manufacturer of		
		WITH STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
	ALL DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	R OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	R OPTION SELECTED *		Yes No N/A
DECODIDITION			
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adequiselected when follow report. More than or * Types of deviations of	d under "justification." Some standards uately justified as appropriate for the sub ving a standard is required under "type o ne page may be necessary. can include an exclusion of a section in	te whether conformance is met. If a section include options, so similar to deviations, th oject device. Explanation of all deviations o of deviation or option selected," "description the standard, a deviation brought out by th the device, or any adaptation of a section.	e option chosen needs to be r description of options " and "justification" on the
		eduction Act Statement	
time for review completing and	ring instructions, searching existing data	ion is estimated to average 1 hour per response a sources, gathering and maintaining the date in. Send comments regarding this burden es- gestions for reducing this burden to:	ata needed, and
Food a Office 1350 H	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spon: required to respond to, a collection displays a currently valid OMB cont	of information unless it

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Department of Health Food and Drug STANDARDS DATA R (To be filled in	Administration REPORT FOR 510(k)s		
This report and the Summary Report Table are to be compleences a national or international standard. A separate report			
TYPE OF 510(K) SUBMISSION			
Traditional Special	Abbreviated		
STANDARD TITLE ¹			
ASTM F2182-11a Standard test method for measurement of radio fi	requency induced heating on or near passive i	mplants	during m
Please answer the following questions		Yes	No
Is this standard recognized by FDA 2?		X	
FDA Recognition number ³		¥ <u>8-227</u>	
Was a third party laboratory responsible for testing conformity in the 510(k)?		X	
Is a summary report ⁴ describing the extent of conformance o 510(k)? If no, complete a summary report table.		X	
Does the test data for this device demonstrate conformity to t pertains to this device?	X		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		X	
Does this standard include more than one option or selection If yes, report options selected in the summary report table.	of tests?		X
Were there any deviations or adaptations made in the use of If yes, were deviations in accordance with the FDA suppleme			
Were deviations or adaptations made beyond what is specifie If yes, report these deviations or adaptations in the summary			X
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.			X
Is there an FDA guidance ⁶ that is associated with this standa If yes, was the guidance document followed in preparation of	this 510k?	X	
Title of guidance: Establishing safety and compatibility of passive	implants in the magnetic resonance (MR) en	vironmer	nt 🗭
 search.cfm The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); 	certification body involved in conformance assessment standard. The summary report includes information of utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional which is necessary before FDA recognizes the standa http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfS search.cfm ⁶ The online search for CDRH Guidance Documents ca www.fda.gov/cdrh/guidance.html	n all stand: al informati ard. Found Standards/	on Lat

		ANDARD CONFORM				
STANDARD TITLE ASTM F2182-11a S	tandard test method for measurement o	f radio frequency induc	ed heating on or nea	r passive in	nplants d	luring m+
	CONFORMANCE	WITH STANDARD SEC	TIONS*			
SECTION NUMBER	SECTION TITLE		1 Vert & B24	CONFORM	ANCE?	
ALL	ALL			Yes Yes	🗌 No	N/A
TYPE OF DEVIATION	OR OPTION SELECTED *					
DESCRIPTION						
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE			CONFORM	ANCE?	
TYPE OF DEVIATION	OR OPTION SELECTED *			Yes	No No	N/A
DESCRIPTION			1996)			
JUSTIFICATION						
SECTION NUMBER	SECTION TITLE		*****************	CONFORM	ANCE?	
TYPE OF DEVIATION	OR OPTION SELECTED *			Yes	No No	□ N/A
DESCRIPTION						
JUSTIFICATION						
explanation is need described and adec selected when follo report. More than c * Types of deviations	ist all sections of the standard and indic led under "justification." Some standard quately justified as appropriate for the su wing a standard is required under "type one page may be necessary. s can include an exclusion of a section in SIS), a deviation to adapt the standard t	s include options, so sin bject device. Explanation of deviation or option so the standard, a deviation	nilar to deviations, the on of all deviations of elected," "description ion brought out by the	e option cho r description " and "justif	osen nee n of optic ication" (eds to be ons on the
	Paperwork I	Reduction Act Stateme	ent			
time for revie completing an	ng burden for this collection of informa wing instructions, searching existing da ad reviewing the collection of informati collection of information, including sug	ta sources, gathering ar	nd maintaining the data and ing this burden es	nta needed,	and	
Food Offic 1350	artment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 sville, MD 20850	required to re	ay not conduct or spon. espond to, a collection rrently valid OMB cont	of informatic		

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rorm	Approvea:	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 ences a national or international standard. A separate report is required for each standard referenced	510(k) t in the 51	hat refer- 10(k).
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 im	plants. (N	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)? 510(k)?	X	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	X	
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.		X
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.		X
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?	X	
Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) env	vironmen	t 🔂
 ¹ The formatting convention for the title is: [SDO] [numeric identifier] [itile 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 ⁶ The online search for CDRH Guidance Documents can www.fda.gov/cdrh/guidance.html 	n all standa al informatio ard. Found Standards/	on at

		DARD CONFORMANCE REPORT TABLE	
STANDARD TITLE	approved 2013) Standard test method for	evaluation of MD image artifacts from	passive implants (Materials)
ASIM F2119-07 (Re		H STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE	H STANDARD SECTIONS	CONFORMANCE?
ALL	ALL		Yes No N/A
	PR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		Yes No N/A
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION C	DR OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adeq selected when follow report. More than o * Types of deviations	st all sections of the standard and indicate ed under "justification." Some standards in uately justified as appropriate for the subje wing a standard is required under "type of o ne page may be necessary. can include an exclusion of a section in th SIS), a deviation to adapt the standard to the	clude options, so similar to deviations, th ct device. Explanation of all deviations o deviation or option selected," "description e standard, a deviation brought out by th	ne option chosen needs to be or description of options n" and "justification" on the ne FDA supplemental
	Paperwork Red	uction Act Statement	
time for review completing an	ng burden for this collection of information ving instructions, searching existing data s d reviewing the collection of information. collection of information, including sugges	n is estimated to average 1 hour per response ources, gathering and maintaining the d Send comments regarding this burden c	ata needed, and
Food Offic 1350	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spor required to respond to, a collection displays a currently valid OMB cor	of information unless it

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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)						
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced						
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 medic	al device	es in the 🃷				
Please answer the following questions	Yes	No				
Is this standard recognized by FDA ² ?	×					
FDA Recognition number ³	# <u>8-124</u>					
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.	X					
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.		X				
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.		X				
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	X					
Title of guidance: Establishing safety and compatibility of passive implants in the magnetic resonance (MR) en	ivironme	nt 🔂				
 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 ⁶ The online search for CDRH Guidance.html 	on all stand al informa lard. Foun Standards	tion d at /				

		DARD CONFORMANCE REPORT TABLE	
STANDARD TITLE ASTM F2052-06e1 S	tandard test method for measurement of m	agnetically induced displacement forc	e on medical devices in the n_{\pm}
	CONFORMANCE WITH	I STANDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION O	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
Construction and distance and a second s			Yes No N/A
TYPE OF DEVIATION O	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
			Yes No N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is needed described and adequ selected when follow report. More than on	t all sections of the standard and indicate w d under "justification." Some standards inclu lately justified as appropriate for the subject ing a standard is required under "type of de le page may be necessary.	ude options, so similar to deviations, tr t device. Explanation of all deviations o viation or option selected," "description	e option chosen needs to be or description of options n" and "justification" on the
	can include an exclusion of a section in the S), a deviation to adapt the standard to the		
	Paperwork Redu	ction Act Statement	
time for review. completing and	g burden for this collection of information in ing instructions, searching existing data so reviewing the collection of information. So ollection of information, including suggesti	urces, gathering and maintaining the d end comments regarding this burden e	ata needed, and
Food a Office 1350 F	ament of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ille, MD 20850	An agency may not conduct or spon required to respond to, a collection displays a currently valid OMB con	of information unless it

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This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced					
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 d	evices 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?	X				
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	X				
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		X			
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.		X			
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		X			
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) e		nt 🔒			
 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 ² The supplemental information sheet (SIS) is addition which is necessary before FDA recognizes the state http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search.cfm ⁶ The online search for CDRH Guidance Documents www.fda.gov/cdrh/guidance.html 	nent to this a on all stand onal informati ndard. Found cfStandards/	lards ion d at			

FORM FDA 3654 (12/10)

	EXTENT OF STANDARD SUMMARY REPO		
STANDARD TITLE ASTM F2213-05 (Rea	pproved 2011) Standard test method for measur	rement of magnetically induced to	orque on medical devices in
	CONFORMANCE WITH STA	NDARD SECTIONS*	
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
ALL	ALL		Yes No N/A
TYPE OF DEVIATION OF	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION OF	ROPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
SECTION NUMBER	SECTION TITLE		CONFORMANCE?
TYPE OF DEVIATION O	R OPTION SELECTED *		
DESCRIPTION			
JUSTIFICATION			
explanation is neede described and adequ selected when follow report. More than or	t all sections of the standard and indicate whether d under "justification." Some standards include of ately justified as appropriate for the subject devi ring a standard is required under "type of deviation the page may be necessary.	ptions, so similar to deviations, the centric sector of all deviations of all deviations of an or option selected," "description	ne option chosen needs to be or description of options n" and "justification" on the
* Types of deviations of information sheet (S	can include an exclusion of a section in the stand IS), a deviation to adapt the standard to the devi	dard, a deviation brought out by th ce, or any adaptation of a section	ne FDA supplemental
	Paperwork Reduction	Act Statement	
time for review completing and	g burden for this collection of information is est ving instructions, searching existing data sources I reviewing the collection of information. Send of ollection of information, including suggestions	s, gathering and maintaining the d comments regarding this burden e	lata needed, and
Food Office 1350	tment of Health and Human Services and Drug Administration of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spor required to respond to, a collection displays a currently valid OMB con	n of information unless it

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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)		
This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) in the 5	that refer- 10(k).
TYPE OF 510(K) SUBMISSION		
Traditional Special Abbreviated		
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 ?		X
FDA Recognition number ³	# Not A	oplicable
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	X	
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).	X	
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 ² 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 	on all stands al informati lard. Found Standards/	on I at

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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)								
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that refer- ences a national or international standard. A separate report is required for each standard referenced in the 510(k).								
TYPE OF 510(K) SUBMISSION								
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 ?		X						
FDA Recognition number ³	# Not Ap	plicable						
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	\boxtimes							
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.	\boxtimes							
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	\boxtimes							
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	\boxtimes							
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		\boxtimes						
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.		\boxtimes						
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		\boxtimes						
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 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 FORM FDA 3654 (1/14) 	cludes inforr levice. al informatic bund at http: ards/search an be found	nation on n which // .cfm at						

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TYPE OF DEVIATION OR OPTION SELECTED *							
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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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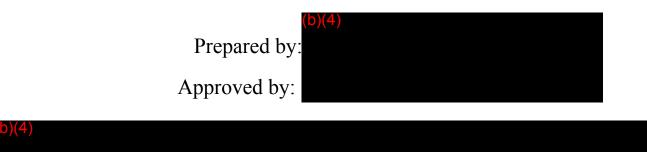
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Freedom Spinal Cord Stimulator (SCS) System

WAA Specifications



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



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3.4 Quality

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

4.0 System Overview



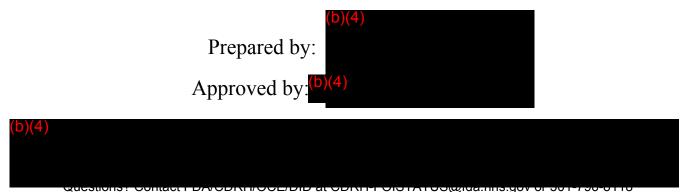
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Freedom Spinal Cord Stimulator (SCS) System

Battery Charger Specifications





Battery Charger Specifications

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Battery Charger Specifications

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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.

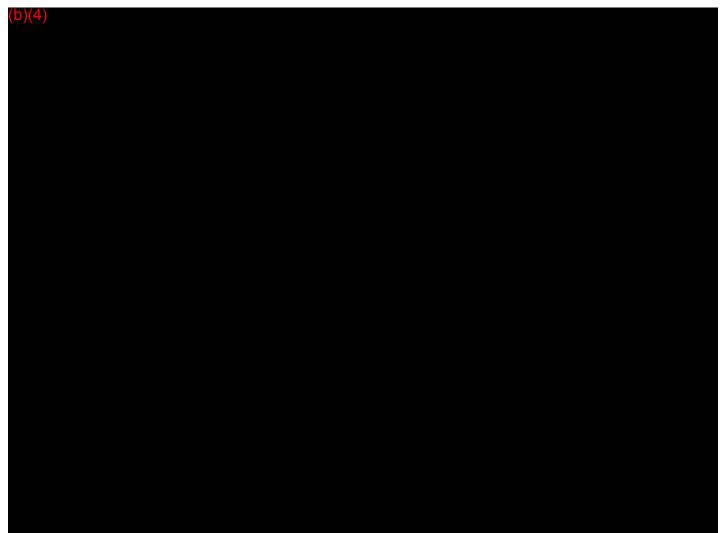
3.4 Quality

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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J.

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 <u>Code of Federal Regulations</u>, 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.

Page 2 - Mr. Rashmi Moza

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> 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,

nh A 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

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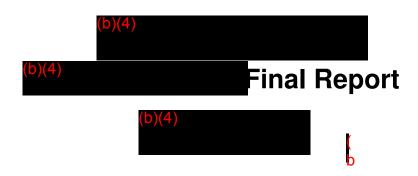
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Accelerated Aging & Package Testing



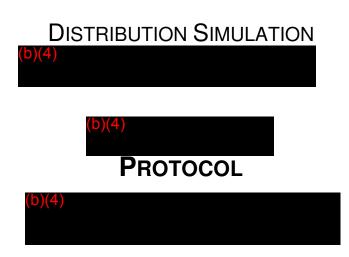
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Stimwave Technologies, Inc.

ASTM D4169-09 Distribution Simulation

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



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-Environments Testing Verification

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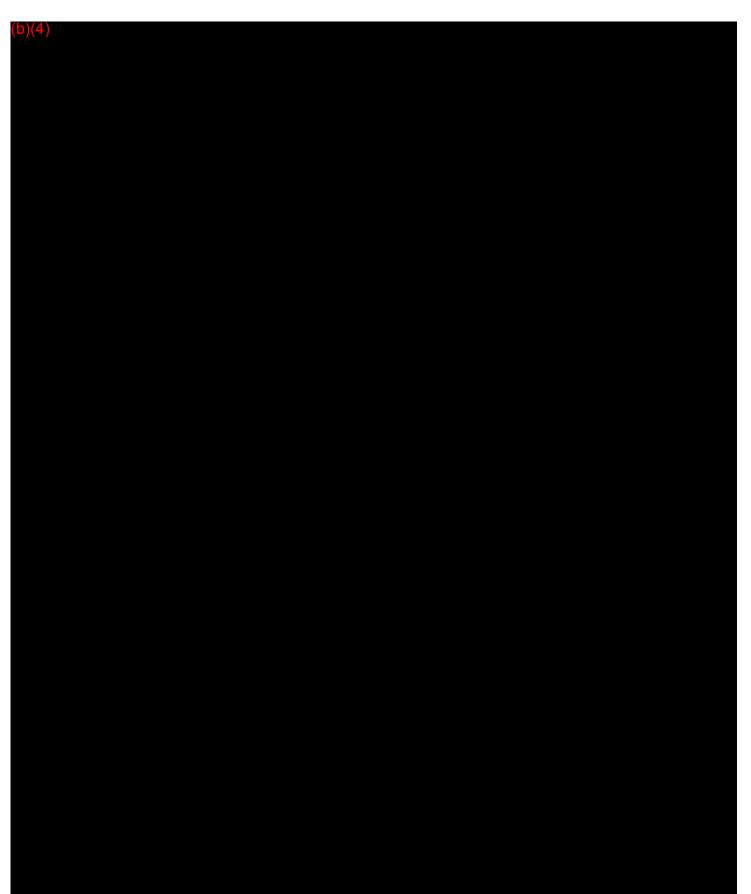


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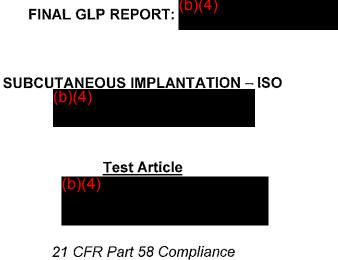
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21 CFR Part 58 Compliance GLP for Nonclinical Laboratory Studies



<u>Sponsor</u> Stimwave Technologies Incorporated 9375 East Shea Boulevard Suite 147 Scottsdale, AZ 86520



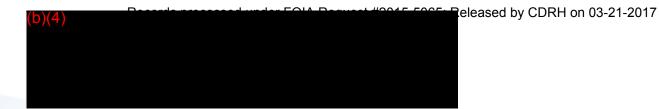
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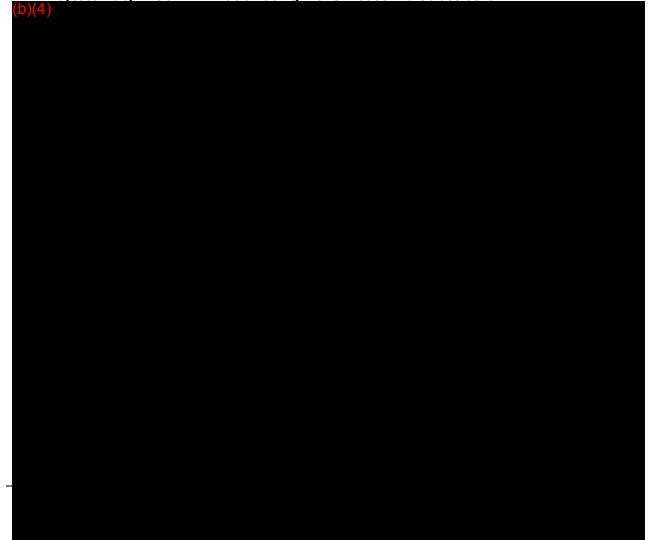
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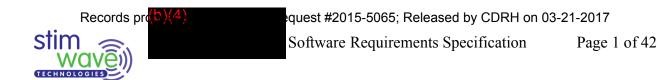








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Freedom Spinal Cord Stimulator (SCS) System

915 Software Requirements Specification

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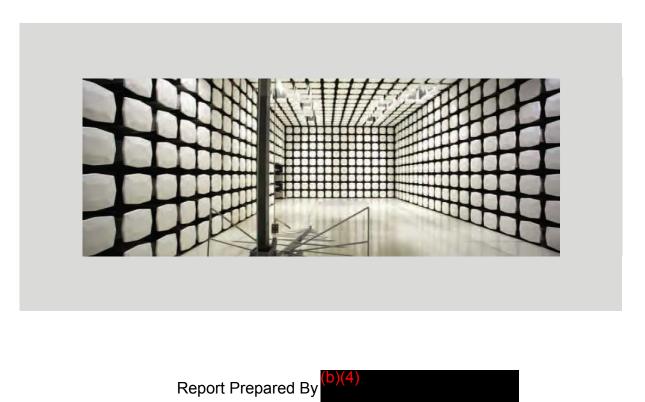
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Stimwave Technologies, Inc. WAA 915 MHz Device FCC 18.305:2013







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



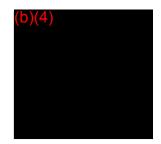


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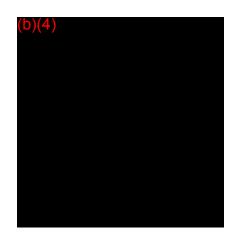






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STIMWAVE TECHNOLOGIES FREEDOM SCS SYSTEM E3 TESTS TO REPRESENTATIVE SECURITY AND LOGISTICAL SYSTEMS IN THE GTRI MEDICAL DEVICE TEST CENTER



Submitted to

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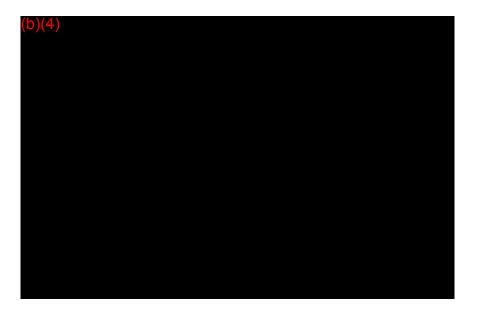
ATTACHMENT 1

E3 TEST PROTOCOL FOR MEDICAL DEVICES TO SECURITY AND LOGISTICAL SYSTEMS



E3 TEST PROTOCOL FOR MEDICAL DEVICES TO SECURITY AND LOGISTICAL SYSTEMS



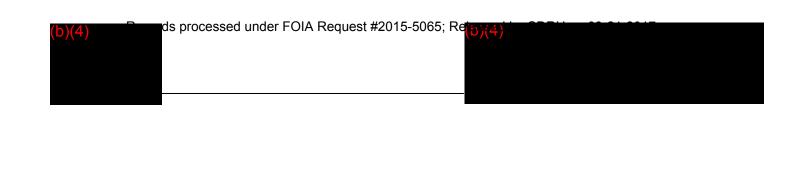








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RF Image Artifact Protocol

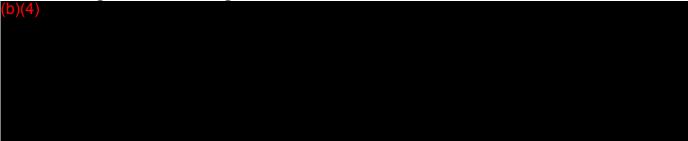
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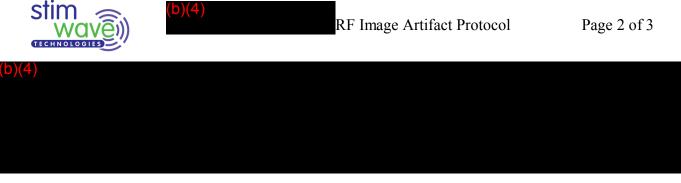


4.0 Materials and Equipment



5.0 Experimental Design





5.2 General Description of Experiment

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6.0 Experimental Procedures



7.0 Data Analysis Techniques



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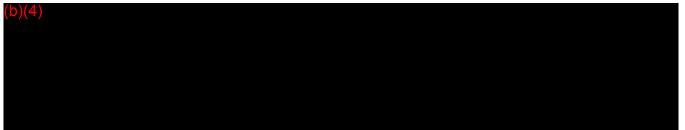


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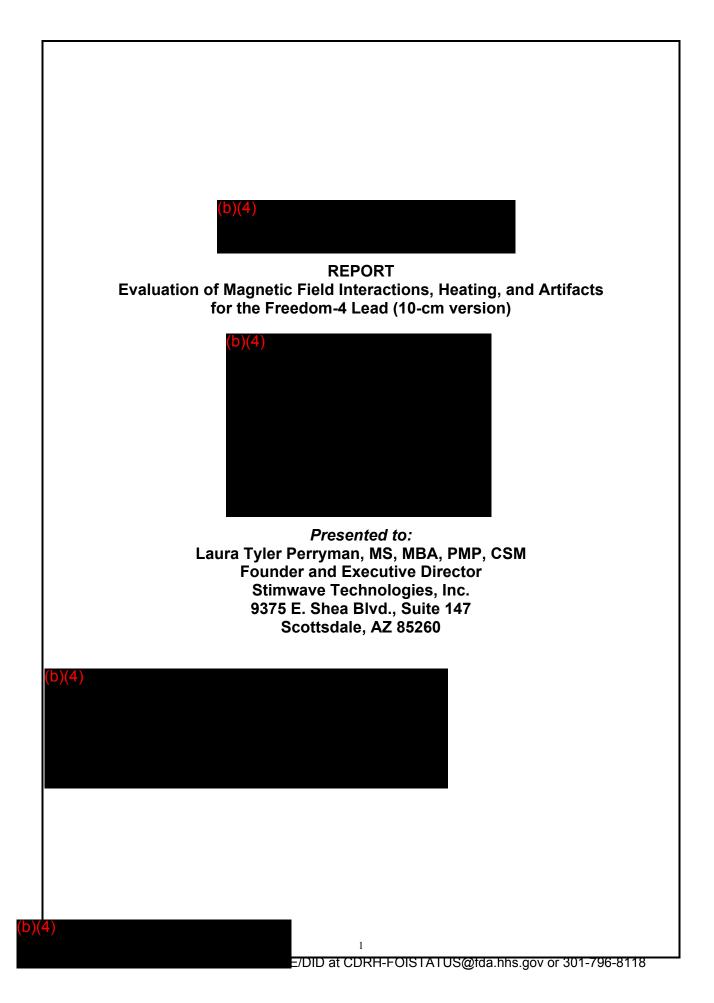
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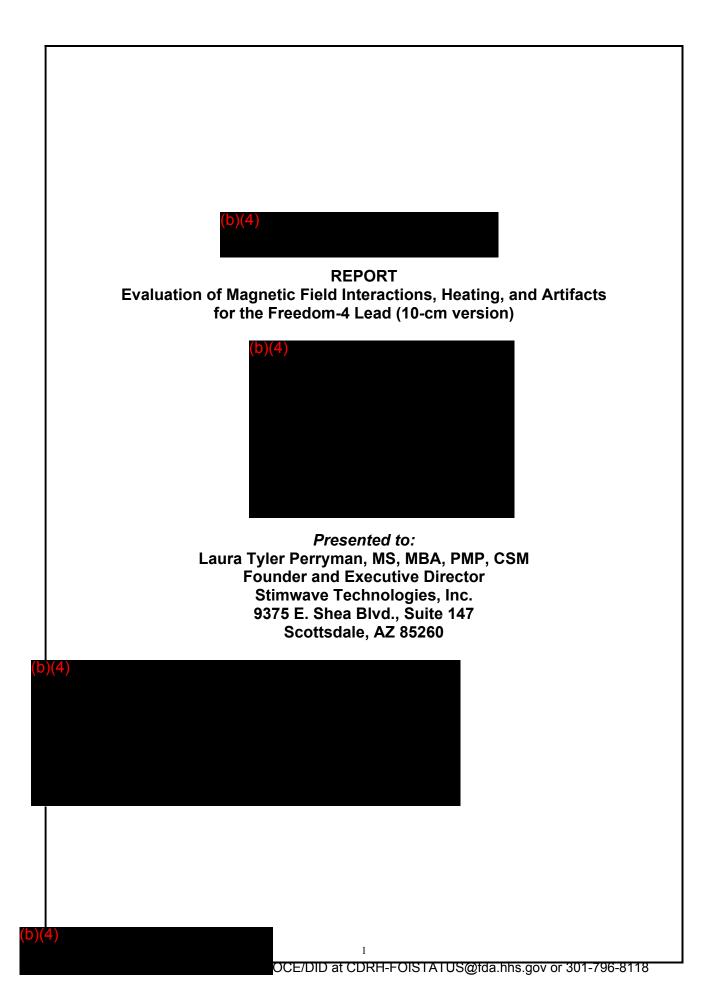
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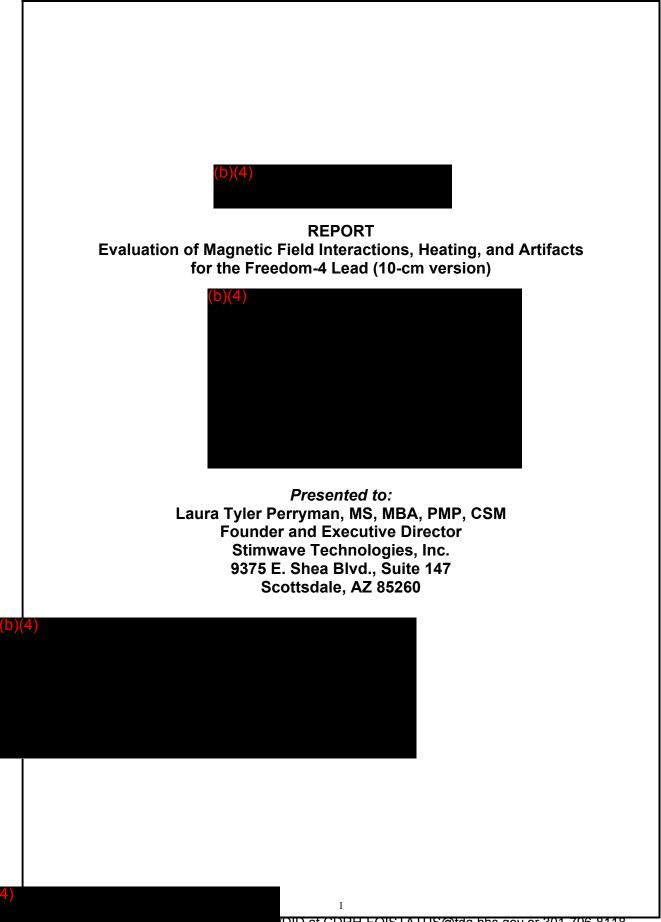
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Assessment of MRI Issues for a 3-T "Immune" Programmable **CSF Shunt Valve**

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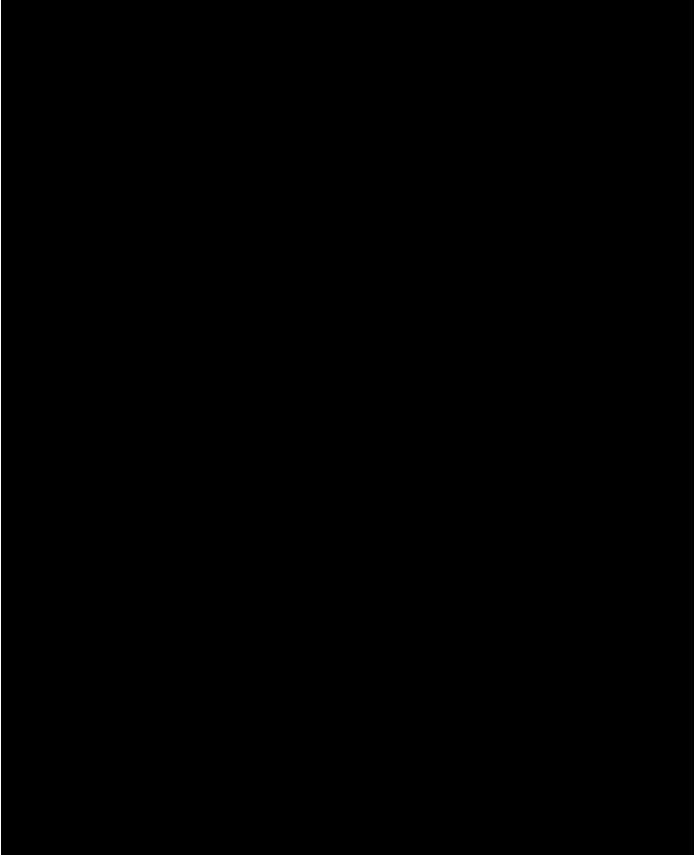
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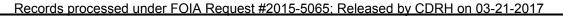


-Functional Verification Inspection

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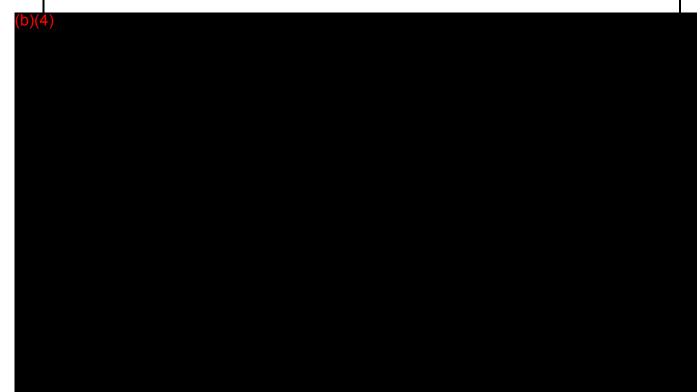


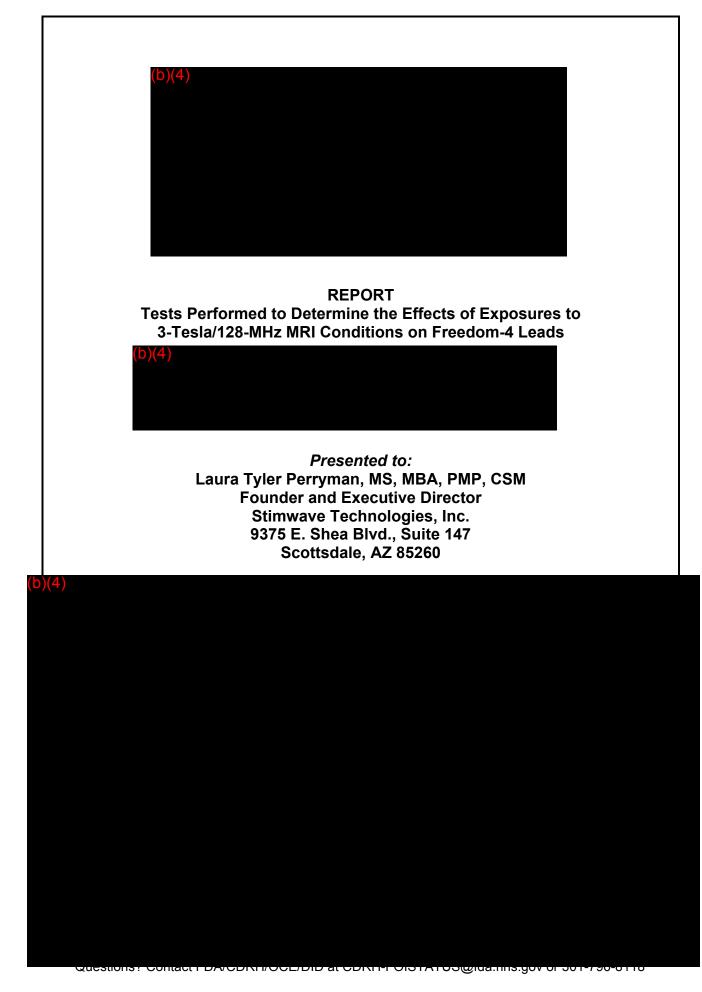
REPORT

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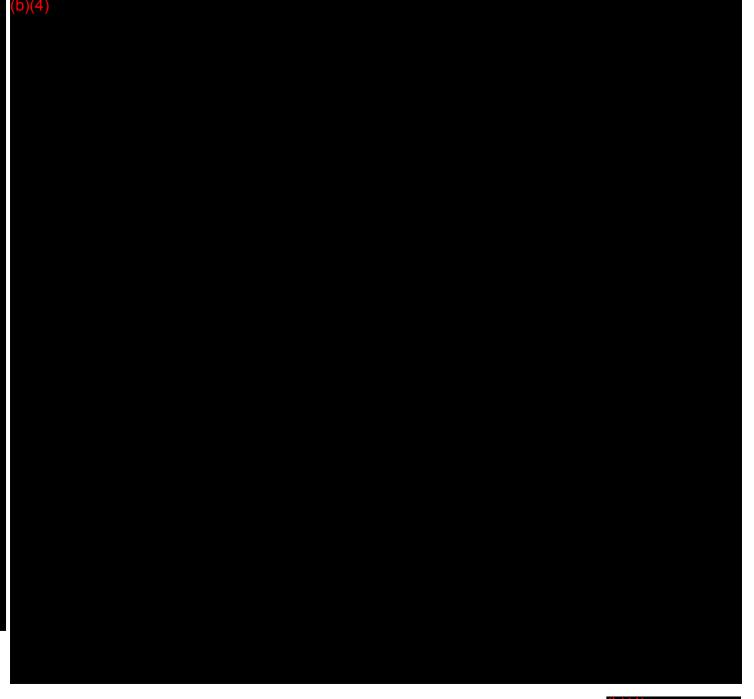


Presented to: Laura Tyler Perryman, MS, MBA, PMP, CSM Founder and Executive Director Stimwave Technologies, Inc. 9375 E. Shea Blvd., Suite 147 Scottsdale, AZ 85260





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



Document Number: 04-0133 Revision: 1

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017

(A)	(b))(4)
)(4)	Test Report	
	Preconditioning and	
	Thermal Shock Test	

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Document Number: 06-0555 Revision: 1

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017



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

(b)(4)

Document Number: 06-0555 Revision: 1

Records processed under FOIA Request #2015-5065; Released by CDRH on 03-21-2017

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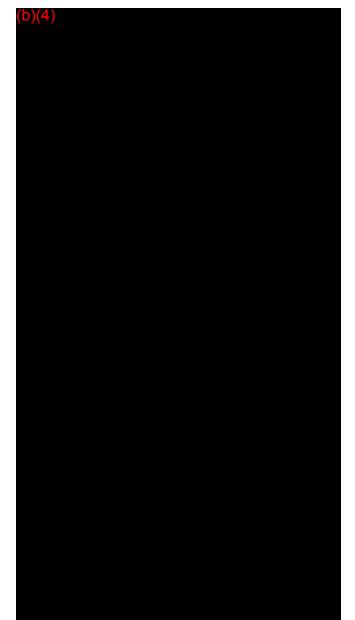
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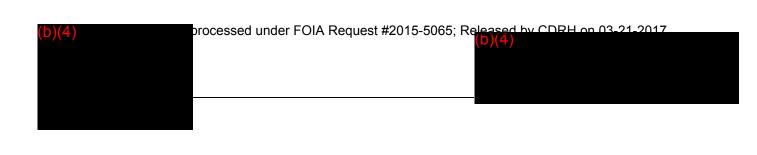
- 1. PURPOSE OF TESTS:
- 2. CUSTOMER:
- 3. DESCRIPTION OF TEST ITEMS:
- 4. PART NUMBER:
- 5. SERIAL NUMBER(S):
- 6. **REFERENCES**:
- 7. QUANTITY OF ITEMS TESTED:
- 8. SECURITY CLASSIFICATION:
- 9. DATE TEST COMPLETED
- 10. TESTS CONDUCTED BY:
- 11. DISPOSITION OF TEST ITEMS:
- 12. TEST ABSTRACT: Drop,Impact,Push 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. :

To perform tests on Medical Units P/N WAA-A001 in accordance with the procedures and specifications cited herein.

Stimwave Technologies, Inc.

Medical Units

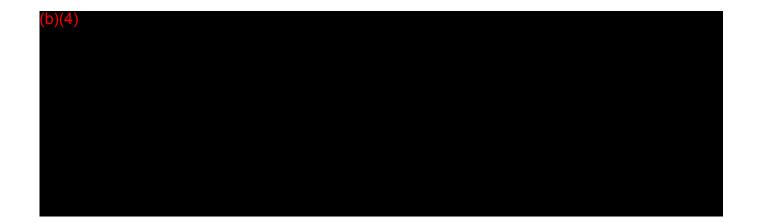






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Pre-Production Risk Management Technical Report Page 1 of 27



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

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Clinical Evaluation Report Stimulation Pulse Characteristics

Page 2 of 23

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.

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Pain

EPIDURAL SPINAL CORD STIMULATION FOR TREATMENT OF CHRONIC PAIN— SOME PREDICTORS OF SUCCESS. A 15-YEAR EXPERIENCE

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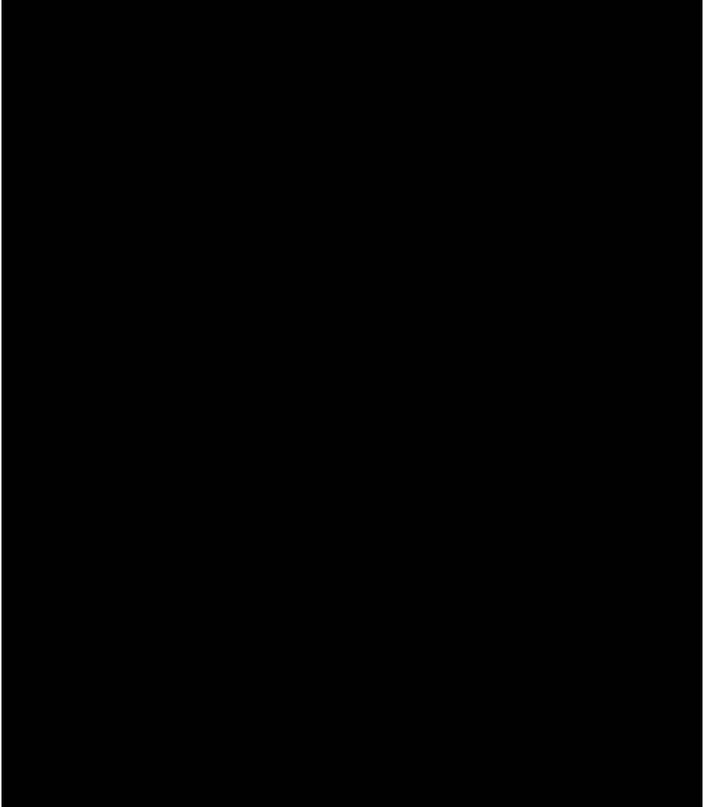
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Clinical Evaluation Report Stimulator Migration 2013

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Injectable spinal cord stimulator system: Pilot study



Malibu Programming Application Usability Page Specification

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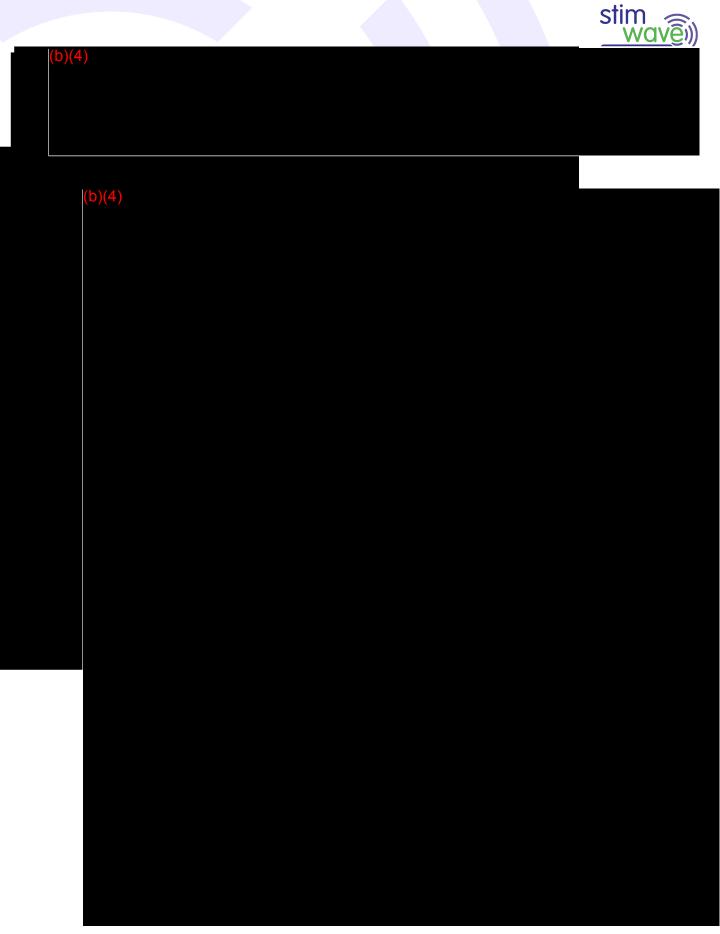


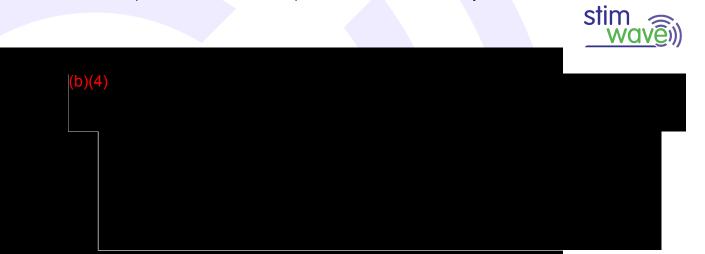
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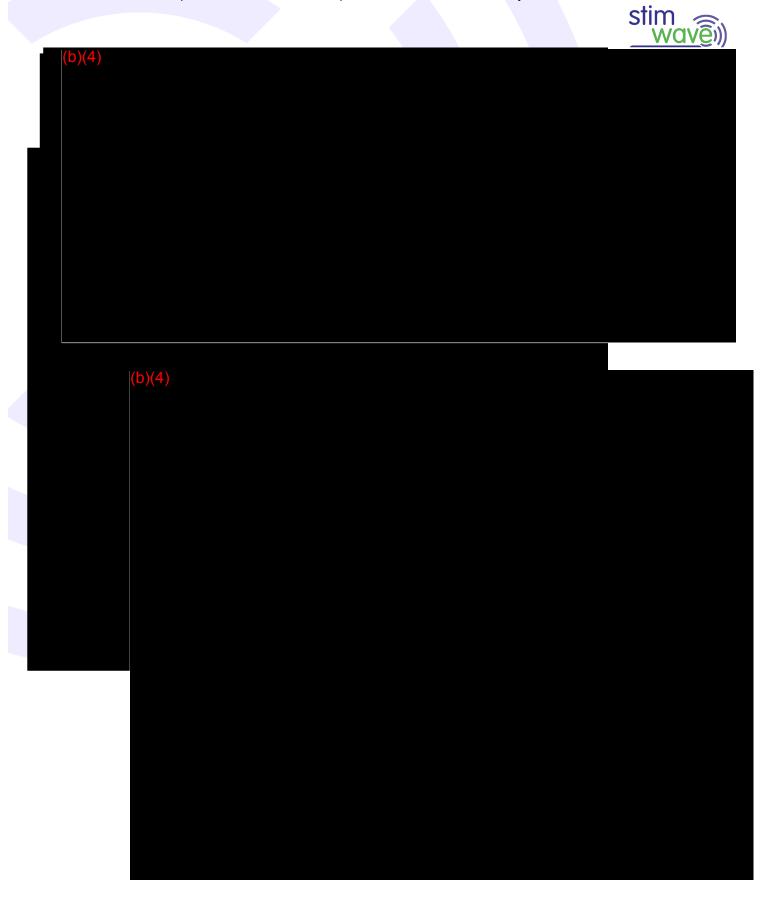




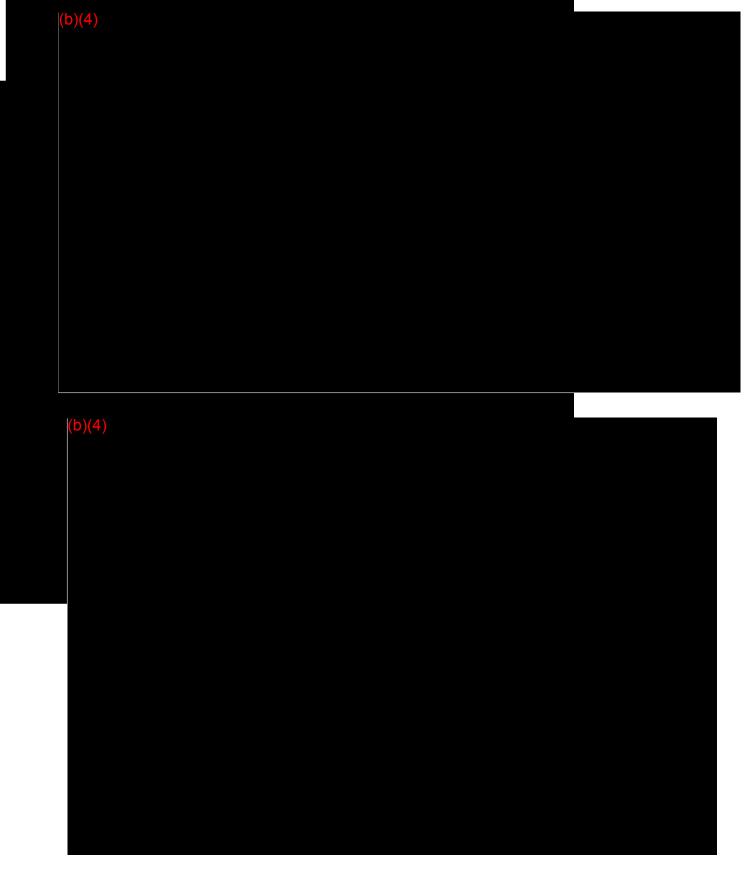
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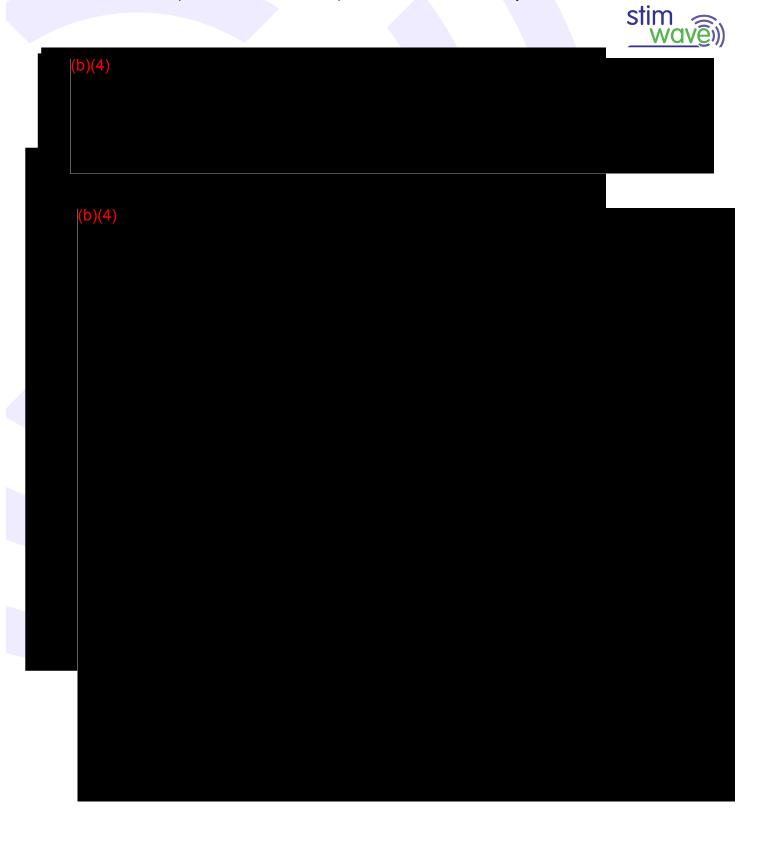








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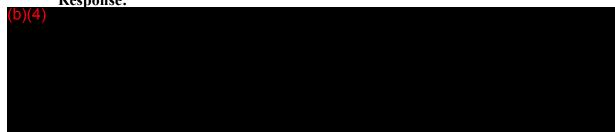
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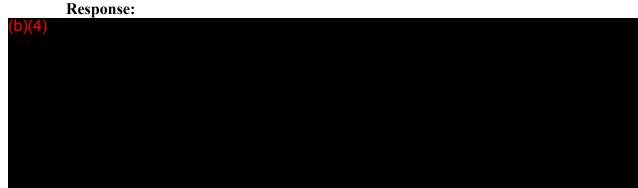














Stimwave Technologies Incorporated 420 Lincoln Road Suite 365 Miami Beach, Florida 33139

September 5, 2014

Food and Drug Administration Center for Devices and Radiological Health Document Mail Cen er – WO66-G609 10903 New Hampsh re Avenue Silver Spring, MD 2)993-0002

Re: K#141399.S001

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The CD provided vith the submission is the official electronic copy of the submission; the eCopy is an exact du plicate of the paper copy.

Kind Regards, Elizabeth Greene



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Design Verification of Stimulation Pulse Characteristics

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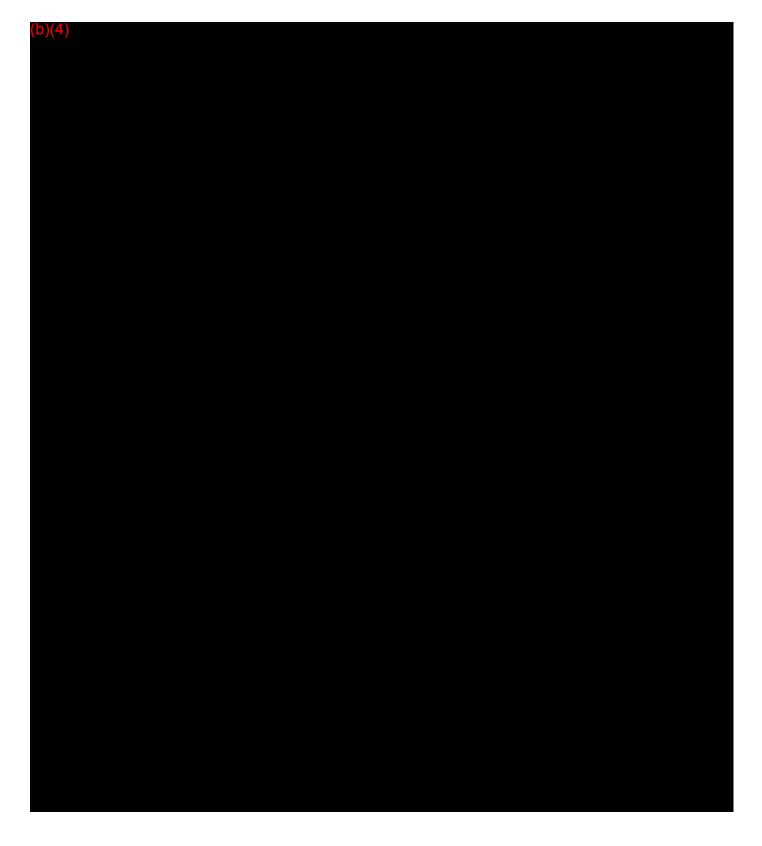
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-Clinical Evaluation Report Stimulator Migration 2013

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FREEDOM SPINAL CORD STIMULATOR

WEARABLE ANTENNA ASSEMBLY

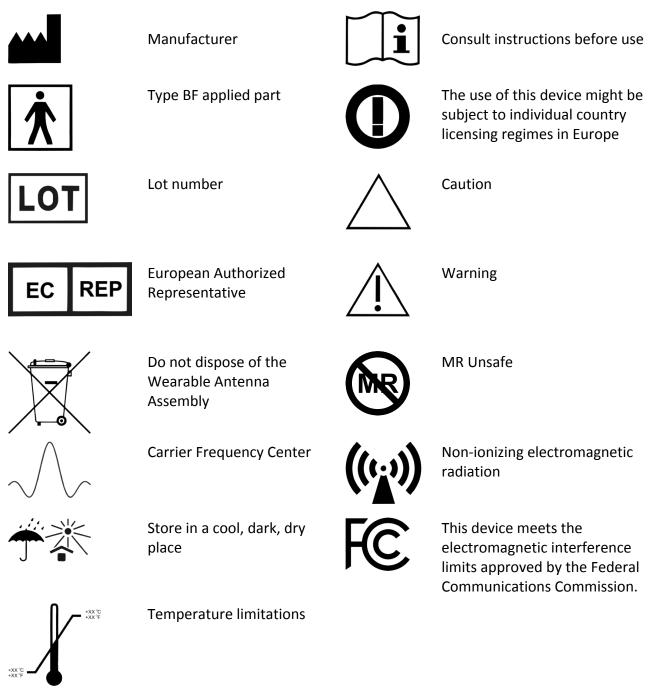
USER MANUAL

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.



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.

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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

Temperature

limitations

Wearable Antenna Assembly Storage Temperature

> +41°F +5°C Temperature limitations

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:

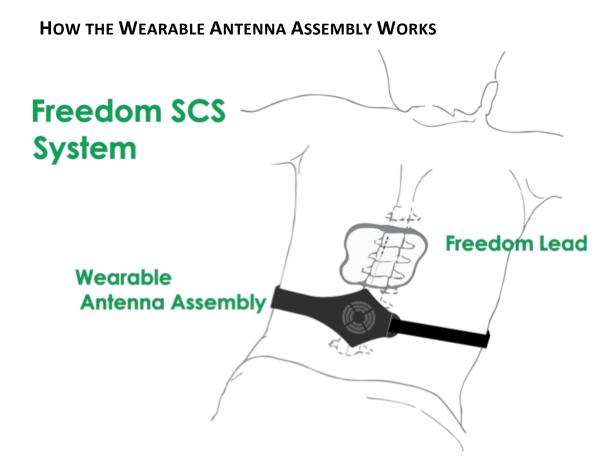
- Undesired change in stimulation, including uncomfortable chest wall stimulation
- Stimulator migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning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



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

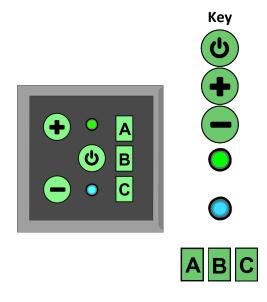
The WAA communicates with your neurostimulator by sending radiofrequency signals. Your neurostimulator only accepts communication from your WAA. The clinician programs your WAA with your specific stimulation parameters. A Bluetooth® connection is made in order to program your WAA.

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



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.

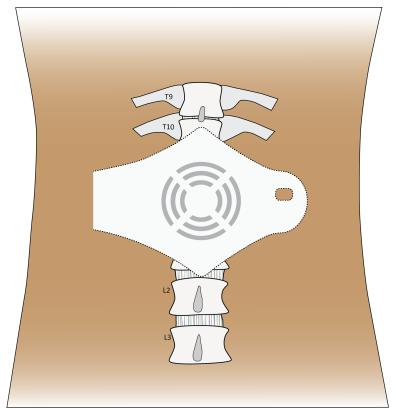
Program Selection Keys – Used to select a set of stimulation parameters pre-programmed by your clinician.

POSITIONING THE WAA

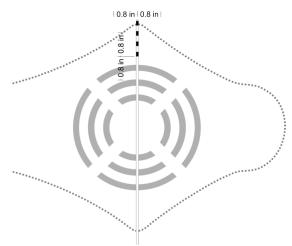
The WAA must be placed over the general region of the implanted receiver within the Stimulator body in order to transfer the optimal amount of power to the device. To place the WAA, attach the WAA band around your midsection with the antenna portion directly in the middle of your lower back. Ensure that 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:

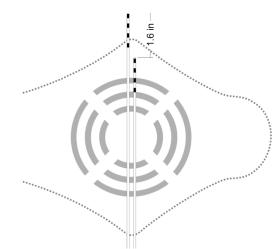
Do not place the WAA directly on your skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.



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.

 $\Delta CAUTION:$

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	Contact your clinician	
find an effective setting		
You will be passing through a security device	Turn off stimulation	
You will be using potentially dangerous equipment	Remove the WAA	
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.

\triangle 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:

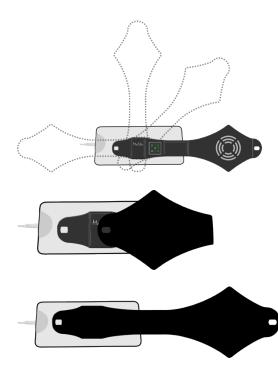
Do not use or wear the WAA while the device is charging. Wearing the WAA while the device is charging may cause harm to you or the system. The WAA will not transmit stimulation while the device is charging.

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.



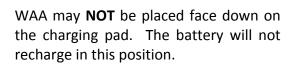


WAA must be placed face up on the charging pad. WAA may be rotated any direction and still effectively charge.



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







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.

Problem	Causes and Actions
Uncomfortable stimulation: You are too uncomfortable with the current stimulation	The selected parameter settings are not suitable for your activity or posture.
to think about how to change it.	Reduce the amplitude on the WAA.
, , , , , , , , , , , , , , , , , , ,	Remove the WAA from your body.
Intermittent stimulation: You feel	The WAA may have a poor connection with the implant. The
stimulation only some of the time.	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	Stimulation is off.
but you think stimulation should be on.	 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	The WAA is not powered on.
light does not turn on. The stimulation	Turn the power ON.
amplitude keys do not respond.	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	WAA is designed to withstand a short drop on a hard surface and
or table.	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 is not waterproof, and water can damage the device.
the WAA or the WAA was dropped into	Immediately remove the WAA from the water, then dry the
water.	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.

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

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	Polyurethane
over a thin layer of clothing at all times)	

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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FREEDOM SPINAL CORD STIMULATOR SYSTEM

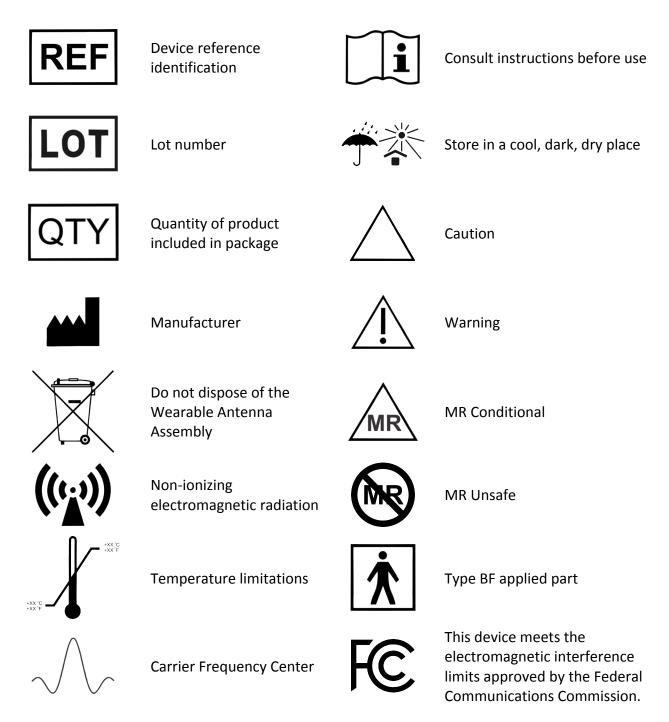
PRODUCT SAFETY GUIDE

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.



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.

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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 highlevel 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
- o 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

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- 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.



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.
- 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

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 2.3°C in a 1.5-Tesla/64-MHz system or 1.9°C 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 inte	The Freedom SCS System is intended for use in the electromagnetic environment specified below. The		
user of the System should assure	e that it is used in suc	h 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	
Harmonic Emissions	N/A – System is	establishments, including domestic	
IEC 61000-3-2	battery powered	establishments and those directly connected to	
Voltage Fluctuations/Flicker	N/A – System is	the public low-voltage power supply network that	
Emissions, IEC 61000-3-3	battery powered	supplies buildings used for domestic purposes.	

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

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Gu	Guidance and manufacturer's declaration – electromagnetic emissions				
The Freedom SCS System is intended for use in the electromagnetic environment specified below. The					
customer or the	user of the System s	nould assure tha	t it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance		
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80MHz 3 V/m 80 MHz to 2.7 GHz	N/A – The system has a permanent antenna 3 V/m	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		

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.

^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.

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	Separation distance according to frequency of transmitter (m)				
output power of transmitter	150 kHz to 80 MHz	150 kHz to 80 MHz 80 MHz to 800 MHz 800MHz to 2.5 GHz			
(W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$		
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 bpsMaximum Data Latency:100msMaximum 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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AUSTRALIAN SPONSOR

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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.

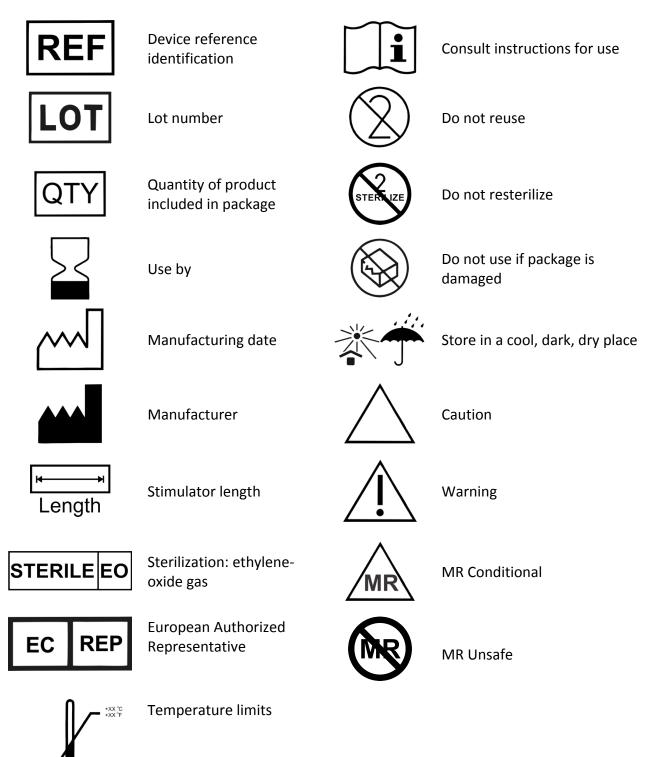


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HOW TO USE THIS MANUAL

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 nonionizing 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.

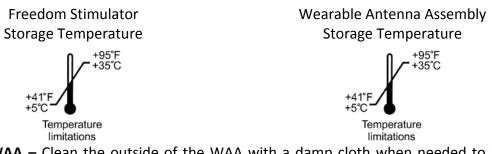
WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

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.



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.

Model number	FRT4 trial version	FRE4 receiver version	
	0 1 2 3	0	
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 1. Specifications of Freedom-4 Stimulators.

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

Table 2. Material in contact with human tissue.

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.

\triangle **C**AUTION:

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.

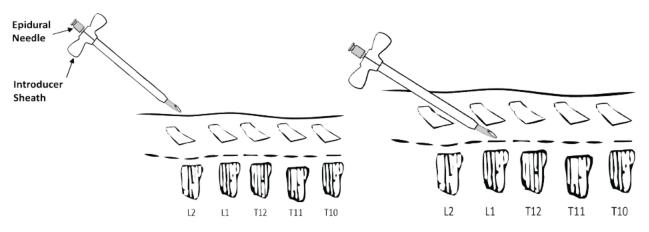


Figure 1. Insert the introducer sheath and needle assembly into the epidural space.

- 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.

\triangle **C**AUTION:

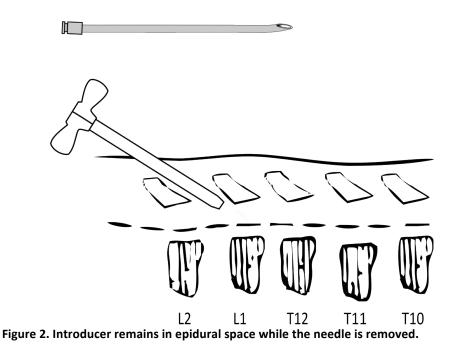
Do not use contrast media. Contrast media might obscure the field of vision.

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.



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.

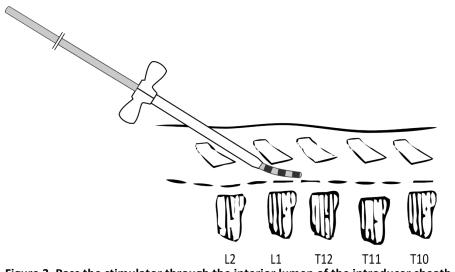


Figure 3. Pass the stimulator through the interior lumen of the introducer sheath.

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).

\triangle **C**AUTION:

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.
- 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.

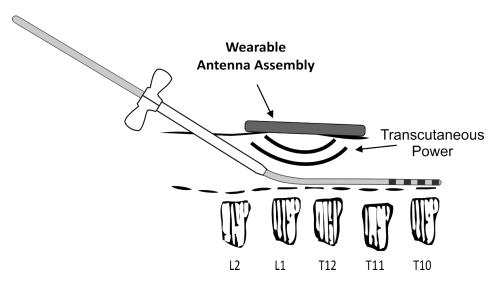


Figure 4. Intraoperative stimulation using the WAA.

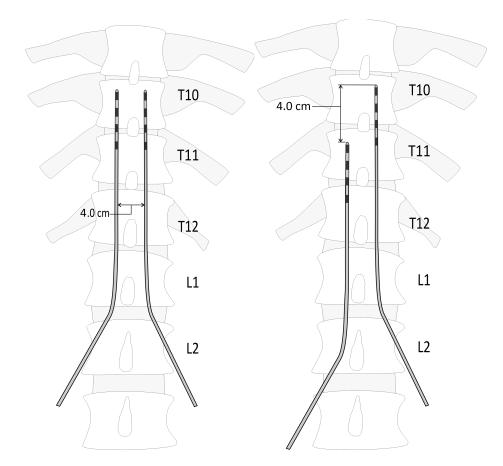


Figure 5. An illustration of two devices separated by no more than 4.0 cm.

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).

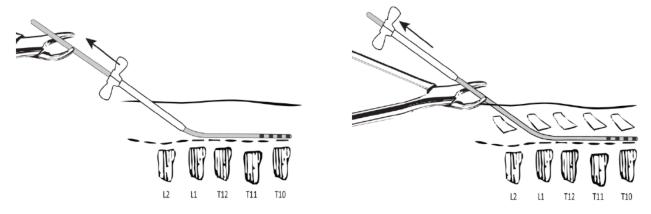


Figure 6. Hold the device using flat, dull tweezers or forceps while removing the introducer.

\triangle 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.

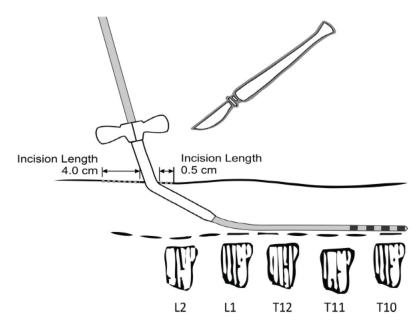


Figure 7. Make a longitudinal incision around the introducer sheath shaft.

\bigtriangleup 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.

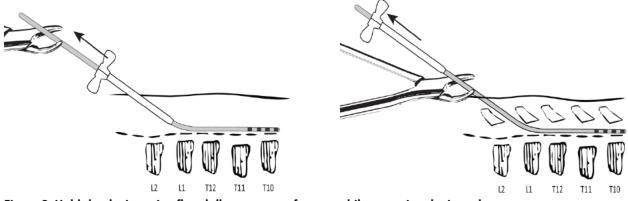


Figure 8. Hold the device using flat, dull tweezers or forceps while removing the introducer.

CAUTION:

Use minimal traction to remove the introducer as sudden removal might dislodge the stimulator.

 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).

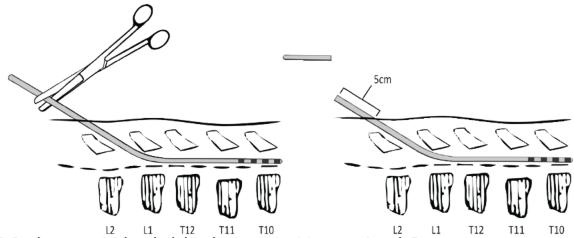


Figure 9. Cut the excess stimulator body length away, maintaining approximately 5 cm.

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.

$\Delta CAUTION:$

- 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.

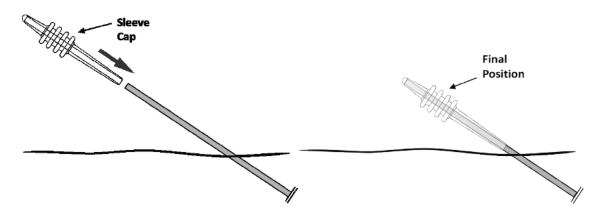


Figure 10. Slide the sleeve cap onto the proximal end of the device.

- 5. Secure the device within the sleeve cap using 2-0 non-absorbable sutures.
- 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.

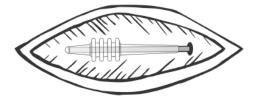


Figure 11. The sleeve cap in the final position and ready for sutures.

- 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.
- 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.
- 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.



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 2.3°C in a 1.5-Tesla/64-MHz system or 1.9°C 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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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

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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 highlevel 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.

<u>The WAA component is MR Unsafe; ensure that the WAA does not enter the MR system</u> <u>room.</u> 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.

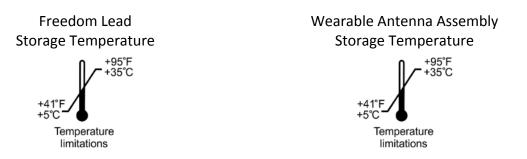
WAA Skin Contact – Do not place the WAA directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must be placed overtop a thin layer of clothing at all times.

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.



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

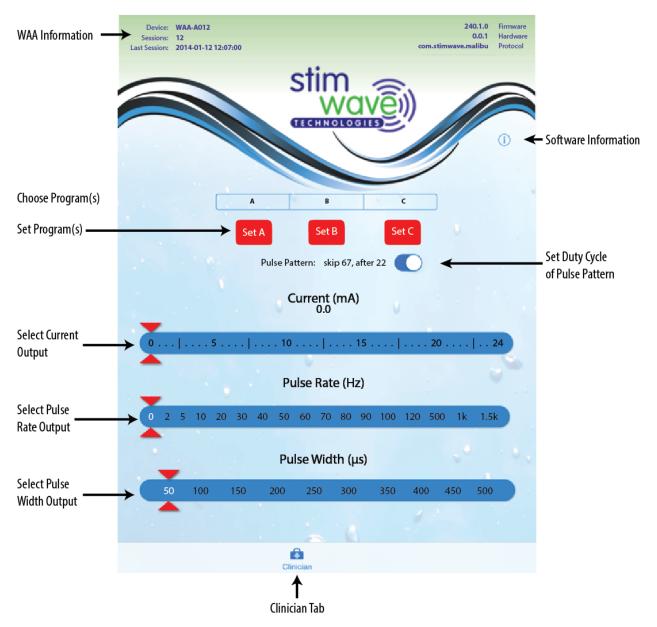
Adverse events that could occur with the Freedom SCS System:

- 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:

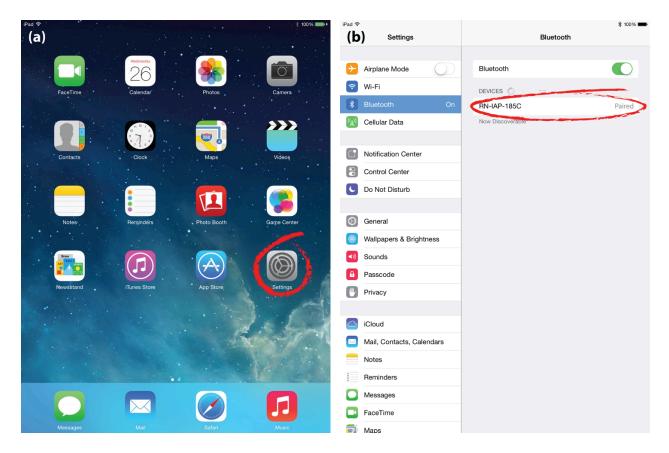
- 1. Ensure that the WAA is powered "OFF".
- 2. While pressing and holding down the "+" button, press the "POWER" button.

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.





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.)

(a)	(b)
stim Wave	stim Wave) erestivotecents
Select An Accessory RN-IAP-185C	A Patient must be assigned to this Malibu unit. Please provide the following information for the patient associated with this Malibu:
Cancel	Patient ID: Device ID Model #
	Save

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 b						
	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 ma						
	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

(b)(4)

MANUFACTURER

(b)(4)			