

SCS ALGOSTIM IPG PFMEA

Document Number 1004467

Revision: B

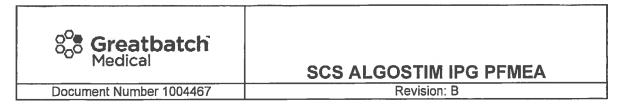
REVISION H	ISTORY		
Revision	Description	Approval	Date
А	Initial Release	G. Routh	2/16/2011
	Updated Processes and	1 11	
В	Electrical Test	hallich	10-28-13

Plan Review Sign-Off

	Name (printed)	Signature	Date
Process	Wesley Omer	1111	
Development		boly h Con	10-22-13
Design	Nick Heitz	21/11/	-2704713
Assurance		MATHE	-2202113
Operations	Eric Mulder	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
Quality		Cof Muly	250(7/3
Value	Aaron Opbroek	11'011	
Stream/Man		Claron &M	10-24-13
ufacturing		Valley Go -	
Product	Dan Kelsch	SEC ATTACK	TMENT
Development		000 411110	1 1000131
Regulatory	Doug Atkins	Du	10-22-2013







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Process	Wesley Omer		
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Quality	222		
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Stream/Man			
ufacturing		a	1
Product	Dan Kelsch	A. M. KM	10/23/13
Development	44772007	Journs 11 MM	- 10/03/13
Regulatory	Doug Atkins		

THE PARTY OF THE P	ost Mitigations		A Action Severity Cocurrence Detection RPN RPN RPN	Sevenity Occurrence Detection NAM	Severity Occurrence Detection NAM	Severity Occurrence Detection N9A	Severity Occurrence Detection N9A	Severity Occurrence Detection N9A
Post Mitigations		Severity		-		 	 	
		Comments						
		Reschon		3 Acc	ო ო	е е е	m m m m	m m m m m
		Severity Occurrence		1 - 3				
		Current Controls		MP, training, downstream handling	MP, training, downstream handling MP, training, downstream handling	MP, training, downstream handling MP, training, downstream handling MP, training, downstream handling	MP, training, downstream handling	MP, training, downstream handling
The second secon		Root Cause of Fallure Currer		not enough epoxy MP, tra	efore	efore in the cavity	efore in the cavity	efore in the cavity efore
		Effect of Fallure Root (ence/dissatisfac				
Semply Algostim IPG - ID Tag Sub Assembly				ID tag escapes from Physician recess in cap battery inconvenie	ID tag escapes from Precess in cap battery ir holder	ID tag escapes from Precess in cap battery in holder	escapes from in cap battery	escapes from in cap battery
בֿ כסס		ID Function of Failure Mode Process Step	10 IID Tad II		o	Attach 1012549	Attach 1012549	Attach 1012549

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insert lead High insert lead insert lead insert lead Stimulation unintended Parts not seated High insert property	compromised. I or intermittent stimulation force, unable to fully ion force, unable to fully	Root Cause of Failure Assembly started with wrong Fart manual loading of parts allows for operator to not load a part assembly not secured prior to loading into header manual loading of parts allows for parts to not be entirely seated	Current Controls Pictures in Work Instruction. Training, visual Inspection Training, visual Inspection Training, visual Inspection Pictures in Work Instruction. Training, visual Inspection	о оссителсе о оссителсе о оссителсе	no hotection	Region Acceptable Acceptable Acceptable	sinemmo⊃ S	Post Mitigations Reccom Action Action Action Taken Severity Occurrence Detection RPM	E E VITIONOS	anerunooO	O Detection NAM	noigeR AsiR
silicone seal damage High insert lead insert lead Stimulation unintended	ion force, unable to fully compromised, or intermittent stimulation	orientation handling/sharp tools	No sharp tools used, training, bore Inspection	2 2	8	8 Acceptable						
plastic stacker Stimulation damage unintended High insert lead insert lead	compromised, I or intermittent stimulation ion force, unable to fully	Weezer technique	Training/Bore Inspection	2	0	8 Acceptable						
		n on fixture	Instruction in MP to clean	1 2	2	4 Acceptable						
ä	f Failure: >		In process inspection	_	2	 						
Displaced ball seal Stimulation spring unintended High insert lead insert lead	n compromised, I or intermittent stimulation ion force, unable to fully	Handling of parts during loading	Training/Bore Inspection/Fixture design	2	7	8 Acceptable						
Crushed ball seal Stimulationspring	Stimulation compromised, unintended or intermittent stimulation	Handling of parts during loading	Training/Fixture Design/bore Inspection	2	7	12 Low					-	
Silicon Ingress - Med Electrical leakage 6600	Modical Modern	ncorrect amount	validated settings on EFD Dispenser	2	2	12 Low					╁	

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Low		Low	Low	Low		Low	Low		Low	Low		Low			Low	Low			
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Instruction in MP to discard	reject	Training, fixture design	Training, visual inspection	EFD settings (high Instruction in MP, validate	settings	Instruction in MP	Visual inspection, instruction	in MP to change after breaks	Instruction in MP	Instruction in MP, validate	settings	Instruction in MP for volume	to mix. Controlled shelf life	date by warehouse	Training instruction in MP	Validation/instruction in MP	to contact	technician/Engineer with	questions or problems
Double cycled part		Part not nested in tool correct	Seal Missing	Incorrect EFD settings (high	pressure, high time)	Incorrect gauge needle	Plugged Tip		Incorrect gauge needle	Incorrect EFD settings (Low	pressure, Low time)	Pot Life			Incorrect Mixing	Robot failure, program issue			
		High insertion force, unable to fully insert lead		Stimulation compromised,	unintended or intermittent stimulation pressure, high time)		Electrical leakage			High insertion force, unable to fully	insert lead				Stimulation compromised,	unintended or intermittent stimulation Robot failure, program issue			
							Stacker Not SI Filled Electrical leakage												
														-					
170		180	190	200		210	220		230	240		250			260	270			

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	SCS Algostim IPG - Port Plug Sub Assy	Port Plug Su	b Assy														
											Po	Post Mitigations	iga	io	5		
₽	ID Function of Process Step	Fallure Mode	Effect of Fallure	Effect of Fallure Root Cause of Fallure	Controls	Severity	eoremuooO	Detection	Risk Region	Comments	Reccommen Action(s) ded Action	Action(s) Taken	Severity	eonemuooO		Risk Region	1
10	10 SCS IPG Accessory Pouch Sealing 1007849	port plug pouch fails to contain units	Physician pouch not sea inconvenience/dis and not taped satisfaction	pouch not sealed, not folded MP, training and not taped	MP, training	.	.	en .	3 Acceptable	ø.						-	1

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										Post Mitigations	tigatio	ns	
D Function of Process Step	Fallure Mode	Effect of Fallure	Root Cause of Fallure	Current Controls	Severity	Occurrence notic	ИФЯ	Risk Region	Commend Reccommend ed Action	Action(s) Taken	Severity	eanemuaaC	Detection
	Low tensile <6lbs	Unable to control stimulation or communicate	Low power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	8 1	e -	о	Acceptable				₩-	-
			Spot Size Too Small	Power Check, Qualified Equipment, Process Specific Equipment		-	ი	Acceptable	!				-
			Spot Size too Big	Power Check, Qualified Equipment, Process Specific Equipment	Γ	<u></u>	6	Acceptable					-
40 101054/			Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test	-	L	o.	Acceptable					
90			Parts contaminated	IP, Print	2	<u></u>	18	Low				\dagger	+
09		Stimulation compromised, unintended or intermittent	Welded wrong location, alignment incorrect	MP, Header Attach	7	<u>.</u>	18	Low					
70		stimulation	Insufficient cover gas	Weld Program, Calibrated Gas Controller, MP	I.,	2	9	Low					
80			Laser out of Focus	Weld Program, Power Check, MP, Tensile Test		Г	თ	Acceptable					
06			Dirty Cover Glass	Weld Program, Power Check, MP, Tensile Test, PM	-	<u> </u>	ი	Acceptable					-
	Loose Spatter	Potential Process Effect of Failure: > 80% First Pass Yield	High Power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	-	2	7	Acceptable					-
110			Welded wrong location, alignment incorrect	MP, Header Attach		-	7	Acceptable					
120			taminated	IP, Print	7	<u>.</u>	4	Acceptable					
130			Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		1_	7	Acceptable					-
140			Fixture Damaged	Qualified fixture, MP, Tensile Test	_	L	7	Acceptable					
			Insufficient cover gas	Weld Program, Calibrated Gas Controller	~	Ī.,	4	Acceptable					
	Excessive Spatter > .005	Potential Process Effect of Failure: > 80% First Pass Yield	Diaode	Weld Program, Power Check, MP	-	2	2	Acceptable					
170			ion, alignment	MP, Header Attach	-		7	Acceptable					
180			Parts contaminated	IP, Print	7	I	4	Acceptable					
190			Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		Γ	7	Acceptable					
200			Fixture Damaged	Qualified fixture, MP, Tensile Test	-	Т	7	Acceptable				+	╀



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SE SE		12.					SE 33	AP.		Weld Program, Power Check, MP, Tensile Test	MP, Header Attach, Final Electrical Test		an an	eck			MP.	Power Check, Qualified Equipment					တ္သ
Weld Program, Calibrated Gas Controller							Weld Program, Calibrated Gas Controller	Weld Program, Power Check, MP		Check	al Ele	į	MP, Leak Check, Weld program	MP, Weld Program, Leak Check			Weld Program, Power Check, MP,	d Equi					Weld Program, Calibrated Gas Controller
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Weld Progr Controller	MP, Header Attach	MP, Header Attach	MP, Header Attach	MP, Header Attach	MP, Header Attach	MP, Header Attach	Progr	Progr	ıjı	Weld Progra	Heade	MP, Header Attach	Leak (Weld	IP, Print, Leak Check		Prog	ar Che		Qualified fixture, MP	int	MP, Weld Recipe	Progr
Weld	MP,	MP.	MP.	MP,	Ā Ā	₫	Weld Prog Controller	Weld	IP, Print	Weld	MP, Test	MP.	MP.	MP.	<u> </u>	₽	Weld	Powe		Ona	IP, Print		Weld Prog Controller
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gas	Sorrect	_	correc	-	_	correct	gas	ation,	DE DE	ation,	ed L-T	9d L-T	gram	setting		og Tec	ation, ocy)	mall		intim T to C	ped	cation	gas
COVE	ed In	mage	ed In	mage	mage	ed In	COVE	ir (Dui	amina	r (Dura	Skipp	Skipp	Pro Pro	ower	tion	landli etc)	r (Dura	T00 S	100 B	naking g of F	amina	ong k	9 00 1
Insufficient cover gas	Parts Loaded Incorrectly	Fixture Damaged	Parts Loaded Incorrect	Fixture Damaged	Fixture Damaged	Parts Loaded Incorrectly	Insufficient cover gas	High Power (Duration, Current, Frequency)	Parts contaminated	Low power (Duration, Diaode Current, Frequency)	Operation Skipped L-Tab not welded	Operation Skipped L-Tab not welded	Wrong Weld Program	Incorrect Power settings	Contamination	Improper Handling Technique (Dropped, etc)	Low power (Duration, Diode Current, Frequency)	Spot Size Too Small	Spot Size too Big	Parts not making intimate contact (Positioning of FT to Can)	Parts contaminated	Welded wrong location, incorrect	Insufficient cover gas
Insu	Parts	Ŧž	Parts	Fixtu	Fixtu	Part	Insu	F. F.	Parts	Cury Cury	Operati welded	Operatic welded	Wro	luco	Cont	Dro (Dro	Curr	Spot	Spot	Parts (Pos	Part	Wek	Insu
	Yield		<u>_</u>	res			Yield				on or		on or			¥ield							
	Potential Process Effect of Failure: > 80% First Pass Yield		Potential Process Effect of	Failure: Multiple Line Failures	ation		Potential Process Effect of Failure: > 80% First Pass Yield				Unable to control stimulation or communicate	Stimulation compromised, unintended or intermittent stimulation	Unable to control stimulation or communicate	Stimulation compromised, unintended or intermittent		Potential Process Effect of Failure; > 80% First Pass Yield				Stimulation compromised, unintended or intermittent stimulation			
	ess El		Ses E	le Lin	e, imt		ess E				trol sti	mpror intern	trol sti	mpror		ess E	*			mpror			
	1 Proc > 80%		l Pro	Multip	lamag		Proc > 80%				to con	ion co	to con	ion co led or	u o	Proc 	npatib			S de se			
	otentia illure:		otentia	illure:	Tissue damage, imitation		otentia illure:				Unable to con communicate	Stimulation compromised, unintended or intermittent stimulation	Unable to con communicate	Stimulation compromised, unintended or intermittent	stimulation	otentia illure:	Bioincompatible			Stimulation unintended stimulation			
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	Tab		ted Up	or Bac	-Tab F		loratic				re L-T		Blow			Cosn	weld (Aver	min ^					
	Damaged L-Tab		L-Tab Welded Upside	Down and/or Backwards	Incorrect L-Tab Position		Weld Discoloration				One or More L-Tab Not Welded		Bad Weld - Blown Weld			Damaged - Cosmetic appearance of can	Insufficient weld penetration (Average	5 and					
	Dam		L-Tal	δ	nco		Weld				One or N Welded		Bad			Dam appe	Feed Through Insufficient weld Welding penetration (Ave	ő ,					
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Weld Program, Power Check, MP,	Weld Program, Power Check, MP, PM	MP, Visual Inspection, Secure Login	Tool Qual, MP, Visual Inspection	Weld Program, Power Check, MP,	alignment MP, Weld Recipe	IP, Print	Qualified fixture, MP	Tool Qual, MP, Visual Inspection	Weld Program, Calibrated Gas Controller	Weld Program, Power Check, MP,	alignment MP, Weld Recipe	IP, Print	Qualified fixture, MP	Tool Qual, MP, Visual Inspection	Weld Program, Calibrated Gas Controller	Weld Program, Power Check, MP,	alignment MP, Weld Recipe	IP, Print	Qualified fixture, MP	Tool Qual, MP, Visual Inspection	Weld Program, Calibrated Gas Controller
Laser out of Focus	Dirty Cover Glass	Beam Seam Tracking Not Following Path	Damaged Tooling Preventing Part Tool Qual, MP, Visual Inspection Contact	High Power (Duration, Diode Current, Frequency)	Welded wrong location, alignment incorrect	Parts contaminated	Parts not making intimate contact Qualified fixture, MP (Positioning of FT to Can)	Fixture Damaged	Insufficient cover gas	High Power (Duration, Diaode Current, Frequency)	8	Parts contaminated	Parts not making intimate contact (Positioning of FT to Can)	Fixture Damaged	Insufficient cover gas	High Power (Duration, Diaode Current, Frequency)	Welded wrong location, alignment incorrect	Parts contaminated	Parts not making intimate contact Qualified fixture, MP (Positioning of FT to Can)	Fixture Damaged	Insufficient cover gas
Premature device failure, explant, unintended revision	surgery*			Tissue damage, imtation						T Potential Process Effect of Failure: > 80% First Pass Yield						Tissue damage, imtation					
				Weld spatter ON PORTIONS OF	FEEDTHRU OTHER THAN THE FLANGE					Weld spatter > .005 on FT surface of can						Weld spatter >.005 on TI can					
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450	460	470	480	490	200	510	520	230	240	550	260	570	280	290	009	610	620	930	640	650	099

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MP, IP, Leak check	MP, Leak Check (Post seam welding)	MP, Leak Check (Post seam welding)	Weld Program, Power Check, MP, Leak Check	Qualified fixture, MP, Leak Check	MP, machine vision and rotation- controlled alignment, Leak Check	MP, Leak Check	MP, Recipe control, Leak Check	MP, Tool Qual, Leak Check	Poke yoke fixture	Weld Program, Calibrated Gas Controller	Weld Program, Power Check, MP,	IP, Print	Weld Program, Power Check, MP,	MP, IP	Tool Qual, MP, Visual Inspection	Weld Program, Power Check, MP,	MP, Weld Recipe	IP, Print	Qualified fixture, MP	Tool Qual, MP, Visual Inspection	Weld Program, Calibrated Gas Controller	MP
Cracked Cermaics	In Complete Weld / Blown Weld/ Cracked Weld		High Power (Duration, Diode Current, Frequency)	Parts not making intimate contact (Positioning of FT to Can)	Beam Seam Tracking Not Following Path	Improper Handling Technique (Dropped, Load, Unload, etc)	Tack weld Sequence Incorrect	Fixture Damaging FT	Part Loaded Incorrectly	Insufficient cover gas	High Power (Duration, Diaode Current, Frequency)	Parts contaminated	Low power (Duration, Diaode Current, Frequency)	Part Handling	Fixture Damaged	High Power (Duration, Diaode Current, Frequency)	Welded wrong location, alignment incorrect	Parts contaminated	Parts not making intimate contact	Fixture Damaged	Insufficient cover gas	Wrong Weld Program
Bioincompatible*	Stimulation compromised, unintended or intermittent stimulation	Premature device failure, explant, unintended revision surgery*	Bioincompatible*	Stimulation compromised, unintended or intermittent stimulation	Premature device failure, explant, unintended revision	surgery*			Potential Process Effect of Failure: > 80% First Pass Yield	Potential Process Effect of Failure; > 80% First Pass Yield				Potential Process Effect of Failure: 60% – 80% First Pass	Yield	Potential Process Effect of Failure: > 80% First Pass Yield						Bioincompatible*
Hermeticity ad post seam	welding)		les .	Cermaic Cracks, etc)					10-pin FT welded in incorrect orientation	Weld Discoloration				FT Pin Damage		Loose Spatter						Blown Weld
670	089	069	200	710	720	730	740	750	760	770	780	790	800	810	820	830	840	820	860	870	880	890



006		Stimulation compromised, unintended or intermittent	Incorrect Power settings	MP, Recipe control, power check	•		4	4 Acceptable			
910		stimulation	FT to enclosure FT slot tolerance stack up - Excessive Gap	tolerance MP, Tool Qual, Leak Check ap			ω	Acceptable			
920		Premature device failure, explant, unintended revision surgery*	Contamination	IP, MP			80	Acceptable			-
930	Damaged - Cosmetic appearance of can	Potential Process Effect of Improper Handling Technique Failure: > 80% First Pass Yield (Dropped, Load, Unload, etc)		MP	+	-	2	2 Acceptable			

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Failure Mode Effect of Failure Root Cause of Failure Current Controls Failure Current Controls Failure Current Controls Current Co	Function of Process				THE PROPERTY OF THE PROPERTY O						Post Mitigations	gat	5	20	K
Communication Communicatio	c	ę		FURN	Current Controls	Severity	eonemuooO	Detection	Risk Region	Reccomme Conded Action	Action(s) Taken	Severity	ecurrence acitacted		Risk Region
Perits not myteriorised Spot Sizes Province Spot Sizes	ab ding	Low tensile <6lbs		(Duration, Diaode Current,	Weld Program, Power Check, MP, Tensile Test	9	-	ဗ							
Parts normative inclinate contact Qualified fixture, MP, Tensile Test 16					Power Check, Qualified Equipment	_	-	_	Т			H	┝	┝	
Potential Process Effect of High Power (Duration) alignment Protection Print	0549			Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		-								
Stimulation compromised, Wielded wrong location, alignment Weld Program, Calibrated Gas Controller 2 18				Parts contaminated	IP, Print		7	<u> </u>	_			r	\vdash	┝	
Protential Process Effect of High Power (Duration, Diaode Current, Weld Program, Power Check, MP, Buttornest Parts northward Insufficient cover gas Weld Program, Power Check, MP, Buttornest Parts northward Manimated Program, Power Check, MP, Buttornest Parts northward Manimated Program, Power Check, MP, Buttornest Parts northward Manimated Process Effect of High Power (Duration, Diaode Current, Weld Program, Power Check, MP, 1 1 2 2 Parts contaminated Parts northward Manimated Development Contact Development Outsificed First Pass Provided wrong location, Diaode Current, Weld Program, Calibrated Gas Controller Process Effect of High Power (Duration, Diaode Current, Weld Program, Power Check, MP 1 1 2 2 Parts northward Manimated MP, Header Attach MP, Tensile Test MAD Meded wrong location, alignment MP, Header Attach MAD, Tensile Test MAD, Header Attach MAD			Stimulation compromised, unintended or intermittent	Welded wrong location, alignment incorrect	MP, Header Attach		7						 		
Potential Process Effect of Positioning of Lab to Card Signature; > 80% First Pass First Pass Potential Process Effect of Positioning of Lab to Card Potential Process Effect of Positioning of Potential Process Effect of			stimulation	Insufficient cover gas	Weld Program, Calibrated Gas Controller		77		+				\vdash	-	1
Dirty Cover Glass					Weld Program, Power Check, MP, Tensile Test		-	.1.					+	-	
Potential Process Effect of Figh Power (Duration, Diaode Current, Weld Program, Power Check, MP, Figh Power (Duration, Diaode Current, Weld Program, Power Check, MP, Figh Power (Duration, Diaode Current, MP, Header Attach Insorted Parts contaminated Parts contaminated Parts contaminated Parts contaminated Parts contaminated Parts not making intimate contact (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 2 Fixture Damaged Program, Power Check, MP 1 1 2 2 Fixture Damaged Parts not making intimate contact (Positioning of L-Tab to Can) Weld Program, Power Check, MP 1 1 2 2 Fixture Damaged Parts contaminated Parts not making intimate contact (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 Parts contaminated Parts not making intimate contact (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 Parts contaminated Process Effect of Parts Loaded Incorrectly MP, Header Attach 2 2 Parts Controller 3 Parts Controller 4 Parts Controller 4 Parts Controller 5 Parts Controller				Dirty Cover Glass	Weld Program, Power Check, MP, Tensile Test, PM		-								
Yield incorrect Welded wrong location, alignment incorrect MP, Header Attach 1 2 Parts contrainisted Parts contract (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 Potential Process Effect of Fixture Damaged Potential Process Effect of Parts nort making intimate contact (Positioning of L-Tab to Can) Weld Program, Power Check, MP 1 2 4 Potential Process Effect of Fixture Damaged Potential Process Effect of Parts nort making intimate contact (Positioning of L-Tab to Can) IP, Print 1 2 4 Potential Process Effect of Parts nort making intimate contact (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 4 Fixture Damaged Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Fixture Damaged Potential Process Effect of Parts Loaded Incorrectly MP, Header Attach 3 1 5 Pailure: Multiple Line Failures Fixture Damaged MP, Header Attach 5 1 5 Galakire, MP, Header Attach 5 1 5 1 5		Loose Spatter		(Duration, Diaode Current,	Weld Program, Power Check, MP, Tensile Test	-	-	2							
Parts contaminated IP, Print Parts not making intimate contact (Positioning of L-Tab to Can) Print				Welded wrong location, alignment incorrect	MP, Header Attach		-	1							
Parts not making intimate contact Qualified fixture, MP, Tensile Test 1 2 Fixture Damaged Qualified fixture, MP, Tensile Test 1 2 Fixture Damaged Insufficient cover gas Meld Program, Power Check, MP 1 1 2 2 Failure: > 80% First Pass Frequency Frequency Melded wrong location, alignment MP, Header Attach 1 2 2 Failure: > 80% First Pass Frequency Melded wrong location, alignment or procest Melded wrong location, alignment or process Melded wrong location MP, Header Attach 1 2 2 4 Fixture Damaged MP, Header Attach 3 2 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 5 1 1 5 Fixture Damaged MP, Header Attach 6 1 1 5 Fixture Damaged Incorrectly MP, Header Attach 6 1 1 5 Fixture Damaged 6 1 1 5 Fixture Damaged 6 1 1 5 Fixture Damaged 7 1 5 Fixture Da					IP, Print	_	2	_	_			H	┝	-	
Fixture Damaged Qualified fixture, MP, Tensile Test 1 2 2					Qualified fixture, MP, Tensile Test		-	L	$\overline{}$					_	
Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4					Qualified fixture, MP, Tensile Test		-					┢	\vdash	H	
Potential Process Effect of First Pass Frequency				Insufficient cover gas	Weld Program, Calibrated Gas Controller		2						-	_	
Yield incorrect incorrect Welded wrong location, alignment incorrect MP, Header Attach 1 2 4 Parts contaminated parts contaminated parts contaminated parts not making intimate contact (Positioning of L-Tab to Can) Qualified fixture, MP, Tensile Test 1 2 4 Fixture Damaged institute of the parts Loaded Incorrectly pown Failures: Multiple Line Failure of the catastrophic failure of the equipment or process) MP, Header Attach 3 2 1 5 1		Excessive Spatter > 005	_		Weld Program, Power Check, MP	-	-	2							
Parts contaminated IP, Print Parts contaminated IP, Print Parts contaminated IP, Print Parts not making intimate contact Qualified fixture, MP, Tensile Test 1 2 Parts not making intimate contact Qualified fixture, MP, Tensile Test 1 2 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 2 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program, Calibrated Gas Controller 3 1 1 5 Insufficient cover gas Weld Program				Welded wrong location, alignment incorrect	MP, Header Attach		-	·							
Parts not making intimate contact Qualified fixture, MP, Tensile Test 1 2 Parts not making intimate contact Qualified fixture, MP, Tensile Test 1 2 Fixture Damaged Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 Fixture Damaged MP, Header Attach 3 2 1 6 Fixture Damaged Parts Loaded Incorrectly MP, Header Attach 5 1 1 5 Insufficient of the catastrophic failure failure of the catastrophic failure of the catastrophic failure failure of the catastrophic failure fai					IP, Print		2					H	H	L	
Fixture Damaged Qualified fixture, MP, Tensile Test 1 2 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 4 ed L- Tissue damage, irritation Parts Loaded Incorrectty MP, Header Attach 3 2 1 6 Fixture Damaged MP, Header Attach 5 1 1 5 Down Failure: Multiple Line Failure of the (catastrophic failure of the equipment or process)					Qualified fixture, MP, Tensile Test		-								
red L- Tissue damage, irritation Parts Loaded Incorrectly MP, Header Attach 3 2 1 6 Fixture Damaged MP, Header Attach 3 2 1 6 Down Failure: Multiple Line Failure of the catastrophic failure of the c					Qualified fixture, MP, Tensile Test	<u> </u>	-	_				t	┝	H	L
ed L- Tissue damage, irritation Parts Loaded Incorrectly MP, Header Attach 3 2 1 6 7 1 6 7 1 8 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1					Weld Program, Calibrated Gas Controller		77	<u> </u>					-	-	
Velded Potential Process Effect of Catastrophic failure of the requirement or process) Fixture Damaged MP, Header Attach 5 1 1 5 Indicate a complete sequipment or process Fixture Damaged MP, Header Attach 5 1 1 5		Damaged L-			MP, Header Attach	က	2	-	П			t	H	┞	
Velded Potential Process Effect of Catalogue of the region of the regi		l ab			MP, Header Attach		-					-		-	
Down Frailure Internation Fixture Damaged MP, Header Attach (catastrophic failure of the equipment or process)		L-Tab Welded		orrectly	MP, Header Attach	2	-	٢	П			\vdash	H	L	
		upside Down and/or Backwards			MP, Header Attach		-	<u> </u>							

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260	Position	I Issue damage, illitation	prectiv		,	- v ~	0 (0	Acceptable	Т
270	Weld	Potential Process Effect of		ihrated Gas Controller	-	2	┿	Accentable	T
	Discoloration	Failure: > 80% First Pass							
280	_	Yield	High Power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP	<u> </u>	2	4	Acceptable	
290			minated	IP, Print		2	4		Γ
300			Low power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test		-	2	Acceptable	
310	One or More L- Tab Not	Unable to control stimulation or communicate	Skipped L-Tab not welded	MP, Header Attach, Final Electrical Test	е	-	e	Acceptable	Π
320	Welded	Stimulation compromised, unintended or intermittent stimulation	Operation Skipped L-Tab not welded	MP, Header Attach,	<u> </u>	-	m	Acceptable	
330	Bad Weld - Blown Weld	Unable to control stimulation or communicate	Wrong Weld Program	MP	က	2 2	12	Low	T
340		Stimulation compromised,	r settings	MP	_	 -	φ	Acceptable	Τ
350		unintended or intermittent		IP, Print		2	12		Γ
360	Damaged - Cosmetic appearance of can	Potential Process Effect of Failure: > 80% First Pass Yield	_	MP	-	2	4	Acceptable	
370 Weld Band Welding		Potential Process Effect of Failure: > 80% First Pass	n, Diaode Current,		-	1 2	2	Acceptable	
$\overline{}$	penetration or			Power Check, Qualified Equipment		_	2	Acceptable	Γ
390 1010550	l ensile?			Qualified fixture, MP, Tensile Test	·	4	ω	Acceptable	
400			correct height	MP, Header Attach		က	φ	Acceptable	Γ
410				IP, Print		7	4		
420			n, alignment	MP, Header Attach		es .	φ	Acceptable	
430			as	Weld Program, Calibrated Gas Controller		-	7	Acceptable	
440			6	Weld Program, Power Check, MP,		~	4	Acceptable	
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460	Max gap to Enclosure	Unable to recharge			ო	-	ო	Acceptable	
470	Damaged Weld Band			MP, Tool Qual, Final Electrical Test	က	1	ო	Acceptable	
480	Weld Band	Unable to recharge	Part damaged during loading	MP, Tool Qual, Final Electrical Test	က	2 1	9	Acceptable	Γ
490	Position			MP, Tool Qual, Final Electrical Test	-	2	9	Acceptable	Г
200	Large gap	Unable to recharge	ading		3	1	Н	Acceptable	
510	between		ly	MP, Tool Qual, Final Electrical Test	Н	-	က	Acceptable	
520	Weld Discoloration	Potential Process Effect of Failure; > 80% First Pass		ntroller	-	1 2	2	Acceptable	
530		Yield	High Power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP		-	2	Acceptable	
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IP, Print	Weld Program, Power Check, MP,	Weld Program, Power Check, MP	MP, Tack Weld	IP, Print	MP, Tack Weld	MP, Tool Qual	Weld Program, Calibrated Gas Controller	MP, Tack Weld	MP, Power Check, Recipe control	٩	MP, Visual Inspection, Tool Qual	MP.	MP, Visual Inspection, Tool Qual	MP, Visual Inspection, Tool Qual	MP, Visual Inspection, Tool Qual	MP, Visual Inspection, Tool Qual	MP, Visual Inspection, Tool Qual	MP, Visual Inspection, Tool Qual						
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	Low power (Duration, Diaode Current, Frequency)	High Power (Duration, Diaode Current, Frequency)	ient		act												-							
	apoe (aode	Welded wrong location, alignment incorrect		Parts not making intimate contact										тесt					rrect			_	
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Parts contaminated	Low power Frequency)	High Power Frequency)	Welded \	Parts contaminated	ts not	Fixture Damaged	Insufficient cover gas	Wrong Weld Program	Incorrect Power settings	Contamination	Loaded Incorrectly		Loaded Incorrectly	Insufficient Vaccum	Pressing Technique Incorrect	Foreign Material	Damage During Handling	Contamination	Damage During Handling	Pressing Technique Incorrect	Loaded Incorrectly		Damage During Handling	
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		al Pro						mpati	tion c ded o ion	ure de unin	ve he 42C)*	rechi:	ve he	42C)	reche	9 9		ve he 42C)*	rechs	ed rec	ve he 42C)*	ech de de	ve he 42C)*	
		Potential Process Effect of Failure: > 80% First Pass	Yield					Bioincompatible*	Stimulation compromised, unintended or intermittent stimulation	Premature device failure, explant, unintended revision surgery*	Excessive heat - severe (above 42C)*	Excess recharge time or increased recharge frequ	Excessive heat - severe	(above 42C)*	Excess recharge time or	creas		Excessive heat – severe (above 42C)*	Excess recharge time or	crease	Excessive heat – severe (above 42C)*	Excess recharge time or increased recharge frequ	Excessive heat – severe (above 42C)*	
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		Excessive Spatter > 005						Bad Weld -	∧ nwo		Overlap of weld band (incorrect	placement)	Bubbles,	wrinkles, >.005				Unbonded Edges			Incorrect Orentation		Perforation of Graphite	
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780	Excess recharge time or increased recharge frequency	MP, Visual Inspection, Tool Qual	-	4 Acceptable	pe e		
790	Unable to control stimulation or communicate	MP, Visual Inspection, Tool Qual	-	4 Acceptable	ple		Ι
800	Unable to recharge	MP, Visual Inspection, Tool Qual	-	4 Acceptable	pje		

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SCS Algostim IPG - H	stim IPG - H	eade	SCS Algostim IPG - Header Stacker Sub Assembly									Post Mitigations	Aitia	atio	S		au 80	
Function of Failure Mode Effect of Failure Process Step		Effect of Failure		Root Cause of Fallure	Current Controls	Severity	өэиөлиээО	Detection	NdB	noigeA AsiA	Reccommende d Action	nde Action(s)	Action(s)	Severity	eonempood	Nda	noigeA Asi5	e
Attach Septum to Strain relief protruding at an Potential Process E Header angle angle	relief protruding at an	Potential Process E First Pass Yield	ffect of Failure: > 80%	Potential Process Effect of Failure: > 80% strain relief not seated properly First Pass Yield (Tooling controlled)	MP, Training, Inspection	2	2	2	8	Acceptable				-	-	-	\vdash	J
Septum protruding unevenly Potential Process Effect of Failure: > 80% 1011489 First Pass Yield	Septum protruding unevenly Potential Process Ef	Potential Process Ef First Pass Yield		Septum not placed correctly	MP, Training, Inspection	-	2	2	4	Acceptable								
Damaged septum Revision difficulty, unable to remove lead from IPG		Revision difficulty, un from IPG	able to remove lead	Handling	MP, Training, Inspection	က	2	2	12	Low							-	
		Implant difficulty, una system, unable to imp	ble to assemble				2		12	Low							-	
Bubbles Stimulation compromised, unintended or intermittent stimulation		Stimulation compromit intermittent stimulation	$\overline{}$	Incorrect amount of material and location of material	MP, Training, Inspection	ဗ	က	2	18	Low				\vdash				
Infection*	Infection*	Infection*		bubbles not removed before cure.	MP, Training, Inspection		က		18	Low				-	-	_	-	1
				strain relief not placed correctly			2		12	Low			r	╁	├	├	╀	Т
Stacker assy placed upside Potential Process Effect of Failure: > 80% loaded in down	Stacker assy placed upside Potential Process Effect down First Pass Yield	Potential Process Effect First Pass Yield	of Failure: > 80%	loaded incorrectly	MP, Training, Inspection	-	2	-	2	Acceptable					 	-		Γ
Not pressed down (uneven) Potential Process Effect of Failure: > 80% Fixturing issue First Pass Yield	Not pressed down (uneven) Potential Process Effect First Pass Yield	Potential Process Effect First Pass Yield	of Failure: > 80%	Fixturing issue	MP, Training, Inspection	-	2	2	4	Acceptable	i							
				assembly technique	MP, Training, Inspection		2		4	Acceptable								
ıt of	ıt of	Potential Process Effect First Pass Yield	t of Failure: > 80%	Potential Process Effect of Failure: > 80% No tension while loading First Pass Yield	MP, Training, Inspection	-	2	-	2	Acceptable								
Si on contact blocks Potential Process Effect of Failure: > 80% Too much silicone First Pass Yield		Potential Process Effer First Pass Yield	ct of Failure; > 80%	Too much silicone	MP, Training, Inspection	-	9	2	9	Acceptable								
				handling	MP, Training, Inspection		9		9	Acceptable								
				Operator technique	MP, Training, Inspection		က		စ	Acceptable								
Battery life reduced (Due to Premature device failure, explant, above 60 C cure)	Battery life reduced (Due to Premature device failu above 60 C cure) unintended revision su	Premature device failu unintended revision su	re, explant, rgery*	Temp Too High	MP, Training, Inspection, IQ	ဇ	2	~	12	Low								
Decreased battery life	Decreased battery life	Decreased battery life								Acceptable				\vdash	\vdash	\vdash	\vdash	



ID Function of Process Step	ſ													
	Failure Mode	Effect of Fallure	Root Cause of Fallure	Current Controls	Severity Occurrence	nottoeted	NdN	Risk Region	Reccomme nded Action	Action(s)	Severity	Occurrence	Detection	Risk Region
10 1A Board level test	Amplitudes incorrect	Stimulation compromised, unintended or intermittent stimulation	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	2	2	12	Low						
20 1009906	Frequencies incorrect	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	e e	2	18	Low					\vdash	
30	RF tuning incorrect	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	2	18	Low						
40	Fuel guage calibration incorrect		Operator technique, incorrect info loaded	MP, Training, Equipment Qual	က	2	18	Low						
20	Charge control error	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info i loaded	MP, Training, Equipment Qual	က	7	85	Low					 	\vdash
09	Current draw measurement error	plant,	Operator technique, incorrect info i loaded	MP, Training, Equipment Qual	3	7	48	Low					\vdash	
70	Temperature sense test error	Temperature sense test error Excessive heat – severe (above 42C)*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	4	2	24	Low						
80 1B Board level test	Outputs are not correct	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	e e	-	o	Acceptable						
90 1009906	Telemetry non-functional	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	е е	-	თ	Acceptable						
100	Compted memory and/or product code	olant,	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	-	თ	Acceptable				\vdash		\vdash
110	Fuel guage/charging non- functional	plant,	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	-	თ	Acceptable						
120 IPG Laser Marking 1010786	Wrong Information / Incorrect artwork	Potential Process Effect of Failure: > 80% First Pass Yield	n Modified	Operational Monitoring Mode - controls blocks that can be edited	1 2	2	4	Acceptable						
130		, -		compare against screen shots in MP	2	_	4	Acceptable				-		†
140			Loaded Wrong Program	compare against screen shots in MP	က		9	Acceptable						
150	Too Dark / Rough Feel to Mark	Potential Process Effect of Fallure; > 80% First Pass Yield	Incorrect Settings (Laser Power)	marking program, Operational Monitoring mode, PM	£	6	6	Acceptable						
160			Program Modified	Operational Monitoring Mode - controls blocks that can be edited	 ←	1	ო	Acceptable						
170			Wrong Laser Focal Plane	shelf and fixtures to control z-height of part	က		ი	Acceptable						
180			Surface Finish of Can (Color and texture)	bead blasting prior to laser mark	က		თ	Acceptable						
190				clean prior to laser mark with 99% IPA	က		6	Acceptable						
200	Too Light	Potential Process Effect of Failure; > 80% First Pass Yield	(Laser Power)	marking program, Operational Monitoring mode, PM	د 8	7	9	Acceptable						
210				Operational Monitoring Mode - controls blocks that can be edited	-		7	Acceptable						
220			Wrong Laser Focal Plane	shelf and fixtures to control z-height of part	က		9	Acceptable				\vdash		



																							:
Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Low	Low	Low	Low	Low
9	, 9	9	9	6	6	9	9	9	9	4	е	6	2	е е	9	9	4	4	12	18	12	12	12
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bead blasting prior to laser mark	PM	clean prior to laser mark with 99% IPA	training, plastic fixtures - softer than shield	training, MP	positioning pins	marking program, Operational Monitoring mode, PM	shelf and fixtures to control z-height of part	IP of enclosures, clean prior to laser mark with 99% IPA	clean prior to laser mark with 99% IPA	Operational Monitoring Mode - controls blocks that can be edited	fixture cut outs for L-Tabs, plastic fixtures - softer than shield	marking program, Operational Monitoring mode, PM	Operational Monitoring Mode - controls blocks that can be edited	clean prior to laser mark with 99% IPA	pins to guide placement of comb	MP - comb inspection	MP	MP, fixture design	MP, without comb flex would be uneven - paste dispense difficult	Tool Qual, comb inspection	Tool Qual	rework per MP, program set - adjustment key removed to prevent changes, electrical test	rework per MP, MP - life check, difficult to dispense, electrical test
Surface Finish of Can (Color and texture)	Cover Glass Dirty	Can Contanimated	Handling	Can not loaded correctly	Fixturing loaded or setup incorrectly	Incorrect Settings (Laser Power, Speed, Freq)	Wrong Laser Focal Plane	Surface Finish of Can (Color and texture)	Can Contanimated	Someone modified Program	Handling	Incorrect Settings (Laser Power, Speed, Freq)	Somebody modified Program	Can Contanimated	Handking	Fixture Damaged	Handling	Fixture Damaged	Spacer Comb not Used	Spacer Comb Damaged	Spacer Comb out of Spec	Wrong Heat Profile (Low temp, Low Airflow, Low Time)	Incorrect activation of flux
			Potential Process Effect of Failure: > 80% First Pass Yield	Potential Process Effect of Failure: >	80% First Pass Yield	Potential Process Effect of Failure: > 80% First Pass Yield					Potential Process Effect of Failure: > 80% First Pass Yield	Potential Process Effect of Failure: > 80% First Pass Yield			Potential Process Effect of Failure: > 80% First Pass Yield		Potential Process Effect of Failure: >	80% First Pass Yield	Unable to control stimulation or communicate	Unable to recharge		Unable to control stimulation or communicate	Unable to recharge
-			Damage Shield	Incorrect laser marking	position	Non uniform marking					Damaged L-Tab	2D Barcode Not Readable			Damaged Filter or FT Pins (must remain straight)		Damaged - Cosmetic	appearance of can	Distance from can edge to top of PCB outside of 0.039"+/-0.012"			Non Wetted Surface	
															PCB to Feedthrough Solder Attach	1000050	OCDEON						
230	240	250	260	270	280	290	300	310	320	330	340	320	360	370		$\overline{}$	\neg	410	420	430	440	450	460

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Electrical leakage Contaminated Pins and/or Pads rework per MP, 2 12 Low cleanroom practices, electrical test	Slimulation compromised, unintended or Evaporation Of Flux rework per MP - 2 12 Low fixture cooled prior to paste deposit, electrical test	Holes Unable to control stimulation or Spacing of Flex hole to Pin rework per MP, PCB IP, 3 2 2 12 Low or communicate Diamater too Large FT IP	Unable to recharge Wrong Heat Profile (Hig temp, High Airflow, How/Low Time)	Electrical leakage Contaminated Pins and/or Pads rework per MP, 2 12 Low clearroom practices, electrical test	Stimulation compromised, unintended or Too Little Paste rework per MP - 2 12 Low dispense dot size check	Unable to control stimulation or Wrong Heat Profile (Hig temp, rework per MP, program 3 2 2 12 Low Ider or communicate High Airflow, How/Low Time) set - adjustment key removed to prevent changes, electrical test	Unable to recharge Contaminated Plins and/or Pads rework per MP, 2 12 Low cleanroom practices, electrical test	Stimulation compromised, unintended or Incorrect activation of flux rework per MP - life 2 12 Low check, difficult to dispense, electrical test	Electrical leakage Moved before solder pool has rework per MP, recipe 2 12 Low cooled cool cycle down to 100C, MP - manual 2 minute cool, electrical test	Unable to control stimulation or Too much paste rework per MP - 3 2 1 6 Acceptable dispense dot size check,	Unable to recharge Air flow too high rework per MP, MP - 6 Acceptable checked at setup, Calibration, electrical test	Electrical leakage Paste Viscosity too Low rework per MP - 6 Acceptable dispense dot size check,	Stimulation compromised, unintended or Operator did not break bridging of rework per MP - 6 Acceptable intermittent stimulation paste prior to heat inspection, electrical test	Uhable to control stimulation or Wrong Heat Profile (Low temp, rework per MP, program 3 2 2 12 Low communicate Low Airflow, Low Time) set - adjustment key
		Voids/Blowholes/Pin Holes contacting the FT pin or	causing other criteria (for example land coverage) to be unacceptable			Joint Surface Rough (fractured/cracked solder or uneven surface from movement during cooling)				Bridging				Incomplete Reflow



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Nozzle Z axis too high	Contaminated Pins and/or Pads	Air flow too low / too high	Wrong Heat Profile (Low temp, Low Airflow, Low Time)	Nozzle Z axis too high	Air flow too high	Paste Viscosity too Low/High	Contaminated Pins and/or Pads	Wrong Heat Profile (Low temp, Low Airflow, Low Time)	Not enough paste	lder p	Contaminated Pins and/or Pads	Wrong Heat Profile (Low temp. Low Airflow, Low Time)	Not enough paste
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Thermistor Incorrect Location Excessive heat – severe (above 42C)* Thermistor Incorrect Location Excessive heat – severe (above 42C)* Thermistor damaged Excessive heat – severe (above 42C)* Excessive heat – severe (above 42C)*	8	Acceptable
Thermistor Incorrect Location Excessive heat – severe (above 42C)* Thermistor not bent in to cavity MP – visual check, MP – 4 3 height check to help determine if under plastic supports, Final Electrical Test Correctly and obscures contact Poor diagnostics Correctly and obscures contact Craphite sheet attach Poor diagnostics Correctly Proceduly pressing metal EFD Tip Training Unintended effect* (metal needed due to orifice size Poor diagnostics and epoxy viscosity) Encapsulation < 50% Excessive heat – severe (above 42C)* Epoxy wicks under support MP – visual check, MP – 4 3	e	Acceptable
Unintended effect correctly and obscures contact Graphite sheet attach fractions into Thermistor During Dispensing Unintended effect (metal needed due to orifice size Poor diagnostics and epoxy viscosity) 50% Excessive heat – severe (above 42C)* Epoxy wicks under support MP – visual check, MP – 4 3	4 w	NG.
Poor diagnostics Correctly and obscures contact Graphite sheet attach Excessive heat – severe (above 42C)* Forcefully pressing metal EFD Tip Training 4 2 into Thermistor During Dispensing Unintended effect* (metal needed due to orifice size Poor diagnostics And epoxy viscosity) Excessive heat – severe (above 42C)* Epoxy wicks under support MP – visual check, MP – 4 3		*
Excessive heat – severe (above 42C)* Forcefully pressing metal EFD Tip Training 4 2 Into Thermistor During Dispensing into Thermistor During Dispensing (metal needed due to orifice size Poor diagnostics and epoxy viscosity) 50% Excessive heat – severe (above 42C)* Epoxy wicks under support MP – visual check, MP – 4 3		
Uninitended effect* Poor diagnostics Excessive heat – severe (above 42C)* [Metal needed due to onlice size and epoxy viscosity) Excessive heat – severe (above 42C)* [Application of the poor of	7	ACC.
Excessive heat – severe (above 42C)* Epoxy wicks under support MP - visual check, MP - 4 3		
supports pressed down with fixture, Final Electrical Test	4 ε	w

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	ruoi uraginosius	Epoxy viscosity too low	Epoxy spec, Final	_	_	20	Acceptable	_
			Electrical Test		Т			
	Unintended effect*	Incorrect amount of epoxy	MP - visual check, MP - weight check, Final Electrical Test		7	16	r Low	
Supports are not seated in can	Potential Process Effect of Failure: > 80% First Pass Yield	Support not held down to correct location	Spring force of fixture, MP - height check	-		2		
		Тоо тисh ероху	MP - visualization during fill, Fixture - holds internals down during fill to prevent push up by epoxy	<u> </u>	2	4	Acceptable	
Epoxy on can	Potential Process Effect of Failure: > 80% First Pass Yield	Handling	MP, fixture limits direct handling of can during dispense	-	2	2	Acceptable	
		Did not clean post dispensing	MP	1,,	7	4	Acceptable	
Battery life reduced (Due to above 60 C cure)	Premature device failure, explant, unintended revision surgery*	Temp Too High	MP, Oven calibration	6	2	3 18	Low	
İ	Decreased battery life	T		\dashv	\dashv	\dashv	-	
Too much epoxy on top surface of support (issue for coil placement)	Potential Process Effect of Failure: > 80% First Pass Yield	Did not clean epoxy off after dispensing	MP	-	2	2 4	Acceptable	
Low tensile <1lbs	Excess recharge time or increased recharge frequency		cleanroom practices, MP - visual inspection	e e	3	3 27	Low	
	Unable to recharge	Too little paste	MP - dispense dot size check, MP - visual inspection	<u> </u>	2	8	Гом	
	Unable to control stimulation or communicate		MP - temp settings, Calibration		2	18	Low	
		Coil moved during cooling	Training, MP - visual inspection	<u> </u>	e e	27	Low	
		Wire was damaged during forming Training, Fixture design/materials	Training, Fixture desion/materials	ļ.,	8	18	3 Low	
Non Wetted Surface	Excess recharge time or increased recharge frequency	Wrong Heat Profile (Low temp, Low Time)	MP - visual inspection, rework per MP, iron Calibration, Final Electrical Test	е	2	12	Low	
	Unable to recharge	Flux Pol/Activation Life (exposed too long)	MP - visual inspection, rework per MP - MP - life check, difficult to dispense, Final Electrical Test	<u> </u>	2	15	Low	
	Unable to control stimulation or	Contaminated Block or Wire	MP - visual inspection,		2	12	; Low	
	communicate		rework per MP,	Щ	2	12	Low	
Voids/Blowholes/Pin Holes	Excess recharge time or increased recharge frequency	ان ا	MP - visual inspection, rework per MP, iron Calibration, Final Electrical Test	ю .ч	2 2			
	Unable to recharge	llock or Wire	rework per MP, cleanroom practices, Final Electrical Test		2	12	Low	
	Unable to control stimulation or communicate	Too Little Paste	MP - dispense dot size check, MP - visual		2	12	Low	
			inepaction Cipal Clockrical		_	_		

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Гом		Гом	Low	Гом	Low	Low	Low	Low	Гом	Гом	Low	Acceptable	Acceptable	Acceptable	Acceptable
2 2 12		2 12	2 12	2 12	2 2 12	2 12	3 3 27	3 27	2 2 12	3 18	3 3 27	2 2 4	2 2 8	1 1 2	1 2 2
MP - visual inspection, rework per MP, iron Calibration, Final Electrical Test		MP - visual inspection, rework per MP, cleanroom practices, Final Electrical Test	rework per MP, MP - paste life check, difficult to dispense, Final Electrical Test	rework per MP, training, Final Electrical Test	MP - visual inspection, 3 rework per MP, iron Calibration, Final Electrical Test	MP - visual inspection, rework per MP, cleanroom practices, Final	MP - visual inspection, 3 rework per MP, fron Calibration	MP - visual inspection, rework per MP	MP - visual inspection, 3 rework per MP, cleanroom practices	MP - set iron temp 3	MP - visual inspection, MP - flux cleaning, cleaner designed to remove specific flux type	MP - visual inspection 1	MP	MP 2	Weld Program, Calibrated 1 Gas Controller
Wrong Heat Profile (High temp, High/Low Time)		Contaminated Block or Wire	Flux Pou'Activation Life (exposed to long)	Moved before solder pool has cooled	Wrong Heat Profile (Low/High itemp, Low/High Time)	Contaminated Block or Wire	Wrong Heat Profile (High temp, Low Time)	Handling - unintended paste deposit or solder iron placement	Handling	Too much heat, too much time	Did not clean properly	Iron touched wrong location	Machine Malfunction, operator error	rect Alignment	Insufficient cover gas
Excess recharge time or increased V recharge frequency	Unable to recharge	Unable to control stimulation or communicate	and and	,	Excess recharge time or increased techarge frequency	Unable to recharge Unable to control stimulation or communicate	Excess recharge time or increased V recharge frequency	Unable to recharge Unable to control stimulation or communicate	Excess recharge time or increased recharge frequency Unable to recharge Unable to control stimulation or communicate	Excess recharge time or increased recharge frequency Unable to recharge Unable to control stimulation or communicate	Premature device failure, explant, unintended revision surgery*	Potential Process Effect of Failure; > 80% First Pass Yield		Tack Weld - incorrect location Potential Process Effect of Failure; > II 80% First Pass Yield	Potential Process Effect of Failure: > 80% First Pass Yield
Joint Surface Rough					Incomplete Reflow		Solder Balls Present		Solder joint FM	Kovar Block Desoldered	Residual Flux Residue	Damaged Other Components	Missing Tack - Missing one or two tacks	Tack Weld - incorrect location	Weld Discoloration
1760	1770	1780	1790	1800	1810	1820	1840	1850 1860 1870	1880 1890 1900	1910 1920 1930	1940	1950 1960	1970 Tack Weld	1980 1010553	1990

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Procession Pro				High Power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP	-	2	Acceptable	
Bloom Webd Premature devote failure, explant, Current Floresting Charles, Produce 1 2 6				Parts contaminated	<u>a</u>	2	4	Acceptable	_
Blown Wed Premature device failure acquart, Depart frog with Property Depart frog minimanded revision aurgent*, Depart frog minimander from the frog minimanded revision aurgent*, Depart frog minimanded revision aurgent*, Depart from the fro				Low power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP	-	7	Acceptable	$oxed{oxed}$
Dimmapet - Correntific Dimmapet - Correct Dimmape		Blown Weld	Premature device failure, explant,	Wrong Weld Program		+	1-	Acceptable	Ţ
Dimaged - Cormolide			unintended revision surgery*	Joint fit up	MP, Tooling	ы	6	Acceptable	L
Dumaged - Cacmetic				Incorrect Power settings	Weld program	7	9	╁	L
Promised Controlled Process Effect of Failure > Import Handing Technique MP				Contamination	R&I	7	ဖ	╁	L
Fucinorm		Damaged - Cosmetic appearance of can	Potential Process Effect of Failure; > 80% First Pass Yield	Improper Handling Technique (Dropped, etc)		\vdash	\vdash	Acceptable	╙
Salutration level of dessicant Permature device failure, explant, unitiended revision surgent, benefit and proceed to room air for MP and Programment of the season of the explant, and the season of the explant of		Incomplete Weld - Lack of Fusion	Potential Process Effect of Failure: > 80% First Pass Yield	Tack Seam too Large	-	-	-	Acceptable	_
Desicant exposed to room at for MP Desicant exposed to room at for MP 12 12 12		Saturation level of dessicant		Desiccant not dried long enough		\vdash	+		$oxed{oxed}$
Description air for MP Permature device faither, explant, Planding Permature device faither, explant, Planding				Oven temp too low	Calibration	7	2		┸
Demaged Dessignant Premature device failure, explant, Handling Miles						-	2		
Premature device failure, explaint, bit enough bake time Calibrated timer, process 1 5 15 15		Damaged Dessicant		Handling		-	-		$oxed{oxed}$
September Part Pa	aam Weld Bake Cycle	Internal moisture > 5000ppm	Premature device failure, explant, unintended revision surgery*		d timer, process	-	-		
Saltings Structucad Excess recharge time or increased Temp too low Calibrated oven, process 1 15 Battery life reduced Excess recharge time or increased Temp Too High Calibrated oven, process 2 1 15 Calibrated oven, process 2 1 15 Calibrated oven, process 2 1 10 Calibrated oven, process 2 2 2 Calibrated oven, process 2	10495			Vacuum pump failure	PM	-	55		L
Temp too bww Calibrated oven, process 1 15				Gasket Failure	PM	-	5		L
Pattery life reduced Excess recharge time or increased Temp Too High Settings					Calibrated oven, process settings	-	12	7 14	_
Insufficient weld penetration Premature device failure, explant, Low power (Duration, Diode Wield Program, Power 2 3 24		Battery life reduced	Excess recharge time or increased recharge frequency		ed oven, process		무		
Spot Size Too Small Spot Check, Specific 1 12		Insufficient weld penetration (Average < 005 and min	Premature device failure, explant, unintended revision surgery*	Low power (Duration, Diode Current, Frequency)	am, Power		\vdash		
Spot Size too Big Spot Check, Specific 12		<.0025)	Bioincompatible*	Spot Size Too Small	Spot Check, Specific Workstation	-	12		
Electrical leakage				Spot Size too Big	Spot Check, Specific Workstation	-	12		
Excessive heat – severe (above 42C)* Welded wrong location, alignment MP, Tool Qual 1 16			Electrical leakage	Parts not making intimate contact	MP, Tool Qual, tack weld	7	24	_	$oxed{oxed}$
Excessive heat – severe (above 42C)* Welded wrong location, alignment incorrect insufficient cover gas Welded Program, Calibrated Gas Controller 1 16 Insufficient cover gas Weld Program, Calibrated Gas Controller 2 24 Laser out of Focus Weld Program, PM 2 24 Electrical leakage Beam Alignment PM, power check 2 24 Beam Alignment PM, Spot Check 2 16 Beam Sam Tracking Not MP, weld program 1 12 Potential Process Effect of Failure: Gas Switching Procedure not Controller System alarms, system 5 1 2 Multiple Line Failures (catastrophic failure correctly followed controller Controller Controller 5 1 2 10 Premature device failure, explant, unintended revision surgery* Britan Alignment or process Britan Alignment or process </td <td></td> <td></td> <td></td> <td>Parts contaminated</td> <td>۵</td> <td>2</td> <td>24</td> <td></td> <td>┸</td>				Parts contaminated	۵	2	24		┸
Insufficient cover gas Weld Program, Calibrated 1 16 Case Controller Caser out of Focus Weld Program, PM 2 24 Electrical leakage Beam Alignment PM, Spot Check 2 24 Beam Seam Tracking Not PM, Spot Check 2 16 Beam Seam Tracking Not PM, Spot Check 2 16 Beam Seam Tracking Not PM, Spot Check 2 16 Beam Seam Tracking Not PM, Spot Check 2 16 Beam Seam Tracking Not PM, Spot Check 2 16 Beam Seam Tracking Not PM, Spot Check 2 16 Following Path Damaged Tooling Procedure not System alarms, system 5 1 2 10 Premature device failure, explant, unintended revision surgery*			Excessive heat – severe (above 42C)*	Welded wrong location, alignment incorrect	MP, Tool Qual	2	24		ļ
Laser out of Focus Weld Program, PM 2 24 Dirty Cover Glass MP, PM, power check 2 24 Electrical leakage Beam Alignment PM, Spot Check 2 16 Beam Seam Tracking Not MP, weld program 1 12 Potential Process Effect of Failure: Gas Switching Procedure not of the equipment or process) Premature device failure, explant, unintended revision surgery*				Insufficient cover gas	Weld Program, Calibrated Gas Controller	-	19		
Dirty Cover Glass MP, PM, power check 2 24				Laser out of Focus	Weld Program, PM	2	24		L
Electrical leakage Beam Alignment PM, Spot Check 2 16				Dirty Cover Glass	MP, PM, power check	2	24		L
Beam Seam Tracking Not MP, weld program 1 12			Electrical leakage	Beam Alignment	PM, Spot Check	7	9		L
Damaged Tooling Preventing Part MP, Tack weid 1 12 Contact Contact Contact Potential Process Effect of Failure: Gas Switching Procedure not of the equipment or process) Premature device failure, explant, unintended revision surgery*				Beam Seam Tracking Not Following Path	MP, weld program	-	12		
Potential Process Effect of Failure: Gas Switching Procedure not Multiple Line Failures (catastrophic failure correctly followed controller controller process) Premature device failure, explant, unintended revision surgery*				Damaged Tooling Preventing Part Contact	MP, Tack weld	-	12		$oxed{oxed}$
Premature device failure, explant, unintended revision surgery*		Incorrect Trace Gas concentration in Glove Box Welder	Potential Process Effect of Failure: Multiple Line Failures (catastrophic failure of the equipment or process)	cedure not		-			<u> </u>
			Premature device failure, explant, unintended revision surgery*						

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	0 Low	Acceptable	Acceptable	Acceptable Low	2 Low	Acceptable	2 Low	Acceptable	-	Acceptable	S Low Acceptable	Acceptable	Ä	3 Low	Acceptable	э Гом	Гом
	2	2	22	2 6	2 2	9	=	2 2		4 4	2 16 8	80	∞	16	2 4	1 16	91
	-	4	4	2 -	0 0	-	7	-		0 0	4 -	-	-	2	1 2	4	4
	System alarms, system controller	System alarms, system controller	System alarms, system controller	Weld Program, Power Check MP, Tool Qual	IP Qualified fixture, MP,	Veld programn, MP	Weld Program, Calibrated Gas Controller	pate	Weld Program, Power Check	Weld Program, Power Check	ng, Weld	Program MP, Tooling, Weld Program	MP, Weld program	_	Wb		
	Gas Mixer Malfunction	Solenoid Valve Failure	Ran out of Helium	High Power (Duration, Diode Current, Frequency) Welded wrong location, alignment incorrect	Parts contaminated Parts not making intimate contact	Fixture Damaged	Insufficient cover gas	Insufficient cover gas	n, Diode	Parts contaminated Low power (Duration, Diode Current, Frequency)	د ا	Seam Tracking	r settings	Contamination	Improper Handling Technique (Dropped, Load, Unload, etc)	Seam Welding Defect	FT Welding Defect
Excessive heat – severe (above 42C)*	Electrical leakage	Premature device failure, explant, unintended revision surgery* Bioincompatible* Excessive heat – severe (above 42C)*	Electrical leakage Premature device failure, explant, unintended revision surgery* Bloincompatible* Excessive heat – severe (above 42C)*	Tissue damage, irritation				Potential Process Effect of Failure: > 80% First Pass Yield			Premature device failure, explant, unintended revision surgery*		Bioincompatible*	Excessive heat – severe (above 42C)*	Electrical leakage Potential Process Effect of Failure: > 80% First Pass Yield	ure, explant, urgery*	Bioincompatible*
_		HE Level > 14	HE Level <10	Excessive Spatter > .005				Weld Discoloration			Bad Weld - Blown Weld/Incomplete Weld				Damaged - Cosmetic	HE Leak >3.386 X 10^-9 ATM CC/Sec	
2330	2340	2350 2360 2370	2380 2390 2410 2420	2430 2440	2450 2460	2470	2480	2490	2500	2520	2530 2540	2550	2560	2570	2590	2600 Hermetic Leak Test	2610 1010778

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2620			Excessive heat – severe (above 42C)*	Damaged Assembly	Weld Program, Power Check, MP	4		16	Low	111		
2630			Electrical leakage		<u> </u>	4	_	16	Low			
2640		Damaged - Cosmetic		Improper Handling Technique (Dropped, Load, Unload, etc)	WP	4	2	ω	Acceptable			
2650	Surface Finishing/Blasting	Non uniform blasting	Potential Process Effect of Failure: > 80% First Pass Yield	Operator technique	Operator training, Pictures in MP, Visual Inspection	e _	က	6	Acceptable			
	1007659	FT Pin Damage		Operator technique	Mask to cover FT pins, LF welding MP	-	4	4	Acceptable		_	
2670		Damage Shield	Potential Process Effect of Failure: > 80% First Pass Yield	Handling	Operator training, Pictures in MP, Visual Inspection	_	4	4	Acceptable			
2680		Damaged L-Tab	Potential Process Effect of Failure: > 180% First Pass Yield	Handling	Operator training, Pictures in MP, Visual Inspection	-	7	7	Acceptable			
2690	Laser Marking	Wrong Information / Incorrect artwork	Potential Process Effect of Failure: > 80% First Pass Yield	Someone modified Program	Operational Monitoring Mode - controls blocks	- 2	2	4	Acceptable			
	1010786				that can be edited							
2700					compare against screen shots in MP	က		9	Acceptable			
2710		Too Dark / Rough Feel to	ect of Failure: >	ings (Laser Power,	\vdash	3	ы	6	Acceptable		L	
		Mark	80% First Pass Yield	Speed, Freq)	Operational Monitoring mode, PM							
2720				Wrong Laser Focal Plane	shelf and fixtures to control z-height of part	60		6	Acceptable			
2730				Finish of Can (Color and	bead blasting prior to	က	_	6	Acceptable	-		
					laser mark		_					
2740				Can Contanimated	clean prior to laser mark with 99% IPA	ო		ი	Acceptable			
2750		Too Light	Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power, P Speed, Freq)	marking program, Operational Monitoring mode, PM	ო	7	9	Acceptable			
2760				Wrong Laser Focal Plane	shelf and fixtures to control z-height of part	ო		9	Acceptable			
2770				Surface Finish of Can (Color and texture)	bead blasting prior to laser mark	က		9	Acceptable			
2780				Slass Dirty	PM	က	_	စ	Acceptable		F	
2790				Can Contanimated o	clean prior to laser mark with 99% IPA	က		9	Acceptable			
2800		Damage Shield	Potential Process Effect of Failure; > 1 80% First Pass Yield	Handling	training, plastic fixtures -	e.	7	9	Acceptable			
2810		Incorrect laser marking	ect of Failure: >	Can not loaded correctly	training, MP	<u>د</u>	က	6	Acceptable		F	
2820		position		\vdash	positioning pins	က		o	Acceptable			
2830		Non uniform marking	Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power, C Speed, Freq)	marking program, Operational Monitoring mode, PM	<u>ო</u>	7	9	Acceptable			
2840				Wrong Laser Focal Plane	shelf and fixtures to control z-height of part	က		9	Acceptable			
2850	2			Surface Finish of Can (Color and the texture)	bead blasting prior to laser mark	က		9	Acceptable			
2860			747	Can Contanimated	clean prior to laser mark with 99% IPA	ო		g	Acceptable			
1		_	_				7			-	-	

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Acceptable	Acceptable	Acceptable	Low	Low	Гом	Low	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable		Low	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Low	Low	Low	Acceptable
4	ო	6	18	8	18	18	_	6	9	ဖ	မ	6	ი		8	2	ю	æ	ω	ω	24	16	16	œ
	1	e E	3	_ص	က	₆		3	2						2	-	-	4	1	_	I	1		_
	-	- 3	9	<u>س</u>	67	<u> </u> "		e e	د	က	3	e e	က		3	1 2	- 3	2	-	-	က	8	7	_
Operational Monitoring Mode - controls blocks that can be edited	fixture cut outs for L-Tabs, plastic fixtures - softer than shield	PM	isual	Inspection at Drill	Train operator to move arbor press lever to hard stop.	Inspection at Drill		Verify training effectiveness, visual inspection after operation, and at silicone apply	Equipment qual, visual inspection	Visual inspection	Visual inspection	al, visual	Verify training effectiveness, visual	inspection after operation, and at silicone apply	MP	Training/visual inspection, LF Welding MP	Verify hole location at drilling. Training, visual inspection	Power Check, Final	Process Qualified on certain Work Station	Process Qualified on certain Work Station	Qualified fixture, MP, Final electrical Test	IP, Print, Final Electrical Test	MP, Final Electrical Test	MP, Final Electrical Test
Someone modified Program	Handling	Too much power	alignment/press missed the pin	header hole not deep enough	not enough force to fully seat the pin	alignment/holes of header to not	meet holes of can	Training	Tooling alignemnt	hole alignment	Handling	Tooling alignemnt	Training - operator		Alignement issues	Loading header, operator technique	Operator technique	Low power (Duration, Diaode Current, Frequency)	Spot Size Too Small. Remove	Spot Size too Big. Change to incorrect spot size	Parts not making intimate contact	Parts contaminated	Damaged lead with process handling	Welded wrong location, alignment MP, Final Electrical Test
	Potential Process Effect of Failure: > 80% First Pass Yield	Internal Damage Due to Heat Potential Process Effect of Failure: > 80% First Pass Yield	Potential Process Effect of Failure; > 80% First Pass Yield	Tissue damage, imtation				Tissue damage, imtation	IPG damage, header damage Potential Process Effect of Failure: > 80% First Pass Yield			Tissue damage, imitation			Tissue damage, imtation	Potential Process Effect of Failure: > 80% First Pass Yield	Potential Process Effect of Failure: > 80% First Pass Yield	Stimulation compromised, unintended or intermittent stimulation				No stimulation output (Under stimulation*)		
	Damaged L-Tab	Internal Damage Due to Heat	oins not ning a sharp	edge is created)				Missing pin (teading to header Tissue damage, imitation misalignment)	IPG damage, header damage			Pin not placed into L-tab hole Tissue damage, imitation (Leading to header	misalignment)		Bowing of Header (Creating sharp edge)	Bent FT Pins		LF Weld Tensile to Contact Block/FT Pin < 0.5lb						
			Header to IPG Pin Press	4005220												-		Lead Frame Welding	1005413/1005414					
7870	2880	2890	2900	2910	2920	2930	οĪ	2950	2960	2970	2980	2990	3000		3010	3020	3030	3040		3060	3070	3080	3090	3100

		insumicient cover gas	Weld Program, Calibrated Gas Controller	-		Acceptable	
		Laser out of Focus	Weld Program, Final Electrical Test	-	-	8 Acceptable	
		Dirty Cover Glass	MP, PM, Power Check, Final Electrical Test	-	<u> ~ </u>	8 Acceptable	
		Beam Alignment	PM, Power Check, Final Electrical Test		<u> ~</u>	8 Acceptable	
Loose Spatter (Leading to a bridge/short between leads)	Stimulation compromised, unintended or intermittent stimulation	High Power (Duration, Diaode Current, Frequency)	Daily Power Check, Final 2 Electrical test	-	7	4 Acceptable	
		on, alignment	MP, Final Electrical Test	-	<u> </u>	4 Acceptable	
		Parts contaminated	IP, Print, Final Electrical	7	1-	8 Acceptable	
	No stimulation output (Under	Parts not making intimate contact	Qualified fixture, MP, Final	7		8 Acceptable	
		Fixture Damaged	Tool Qual, MP, Final	-		2 Acceptable	
		Insufficient cover gas	Weld Program, Calibrated	-	1	2 Acceptable	
			Gas Controller, Final Electrical Test				
Excessive Spatter (Leading to a bridge/short between	Stimulation compromised, unintended or intermittent stimulation	High Power (Duration, Diaode Current, Frequency)	Daily Power Check, Final 2 Electrical test	-	2	4 Acceptable	
leads)		Welded wrong location, alignment incorrect	MP, Final Electrical Test	-	<u> </u>	4 Acceptable	
		Parts contaminated	IP, Print, Final Electrical Test	7		8 Acceptable	
	No stimulation output (Under stimulation*)	Parts not making intimate contact	Qualified fixture, MP, Final electrical Test	7		8 Acceptable	
	a	Fixture Damaged	Tool Qual, MP, Final Electrical Test	-		4 Acceptable	
		Insufficient cover gas	Weld Program, Calibrated Gas Controller, Final Electrical Test	-		4 Acceptable	
Damaged Lead	Stimulation compromised, unintended or intermittent stimulation	Parts Loaded Incorrectly	MP, Visual Inspection, 2	2	+	4 Acceptable	
	No stimulation output (Under stimulation*)	Fixture Damaged	Tool Qual, MP, Final Electrical Test	-		4 Acceptable	
Lead Welded Upside Down and/or Backwards	Potential Process Effect of Failure: > 80% First Pass Yield	Parts Loaded Incorrectly	MP, Visual Inspection, 1 Periodic Tensile Test	-	2	2 Acceptable	
		Fixture Damaged	Tool Qual, MP	-	<u> </u>	2 Acceptable	
Incorrect Lead Position	Potential Process Effect of Failure: > 80% First Pass Yield	Fixture Damaged	MP, Visual Inspection, 1 Periodic Tensile Test	-	2	2 Acceptable	
3		Parts Loaded Incorrectly	MP, Visual Inspection, Final Electrical Test	-	.,	2 Acceptable	
Weld Discoloration	Potential Process Effect of Failure; > 80% First Pass Yield	Insufficient cover gas	Daily Power Check, Recipe Control, Visual Inspection, Calibrated gas controller	-	2	2 Acceptable	
		High Power (Duration, Diaode Current, Frequency)	Daily Power Check, Recipe Control, Visual Inspection.	-	ļ.,	2 Acceptable	
		Parts contaminated	IP, Print	2		4 Acceptable	



Acceptable		Acceptable	Acceptable	Acceptable	According	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Гом	Гом	Low	Гом	Low	Low	Low
7		2	7	7	c	7	7	2	7	4	7	4	4	4	4	4	۵	2	4	4	4	24	24	24	24	54	54	54
	-	-		-	7			-		I _a ,	7	7		Γ	1		Ī.,	7	Ī.,	2		4		Ī.,	T.,	l	l	Ι
	-	2 1		2			-	2	-	2	-	2 1	<u> </u>		_	_	2	-	7	2	-	3 2	7	2	12	2	2	2
Daily Power Check, Recipe Control, Visual	Inspection,	MP, Visual Inspection, Final Electrical Test	MP, Visual Inspection, Final Electrical Test	Ę.	MD Visual Inspection	Final Electrical Test	MP, Visual Inspection, Final Electrical Test	MP, Visual Inspection, Final Electrical Test	MP, Visual Inspection, Final Electrical Test	IP, Print, Final Electrical Test	MP, Visual Inspection	MP, Visual Inspection, Final Electrical Test	MP, Visual Inspection, Final Electrical Test	Tool Qual, MP, Visual Inspection, Final Electrical Test	MP, Visual Inspection, Final Electrical Test	MP, Final Electrical Test	MP, Final Electrical Test	Power check, MP, Visual Inspection	MP		MP, Visual Inspection, Final Electrical Test	Visual Inspection to MP pictures	Clean surfaces, prime surfaces	Clean surfaces, prime surfaces	MP	Oracle/Inventory Control	Operatory training to MP, visual inspection	verify oven temp,
Low power (Duration, Diaode Current, Frequency)		Operation Skipped Lead not welded	Operation Skipped Lead not welded	Incorrect Start location	prisacoma pointe percente per	read daileged during processing	Incorrect Start location	Wrong Weld Program	Incorrect Power settings	Contamination	Improper Handling Technique (Dropped, etc)	Trimming	Excessive tweezing	Fixturing damage	Excessive tweezing	Handling	Lead Frame damaged during loading	High power	Locations	Operator targeted wrong location	Operator targeted wrong location	Not enough epoxy	dirty can	dirty header	not cured long enough	Expired Epoxy	Header alignment	temp not high enough
		Stimulation compromised, unintended or intermittent stimulation	No stimulation output (Under stimulation*)	Stimulation compromised, unintended or			No stimulation output (Under stimulation*)	Stimulation compromised, unintended or intermittent stimulation	No stimulation output (Under stimulation*)	1100	Potential Process Effect of Failure: > 80% First Pass Yield	Stimulation compromised, unintended or intermittent stimulation			No stimulation output (Under stimulation*)			Potential Process Effect of Failure: > 80% First Pass Yield		Stimulation compromised, unintended or intermittent stimulation	No stimulation output (Under stimulation*)	Unable to control stimulation or communicate	Stimulation compromised, unintended or intermittent stimulation	Premature device failure, explant, unintended revision surgery*				
		One or More Lead Not Welded		Bad Weld - Misalignment	(Simple)			Bad Weld - Blown Weld (Unwelded)				Damaged/Touching lead						Discoloration on header	_	Welded wrong spot (Starting point)		Tensile < Spec						
			1_	•	_				T					,					····				1008609					
3360		3370	3380	3390	3400		3410	3420	3430	3440	3450	3460	3470	3480	3490	3500	3510	3520	3530	3540	3550	3560	3570	3580	3590	3600	3610	3620

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	Acceptable	Acceptable	Acceptable	Low			Low					Low		Low						Low					Low						Acceptable
1		4	4	12			12					18		12						12					12						9
N		7		2			_					7		_						T -					2						7
· •		1 2	7	3 2			2					3		7						7					3 2						- 3
verny oven temp,		Operator training, Visual Inspection	Operator training, Visual Inspection	lerial as	Train to process steps	Operator training	Cure 1st fill, room temp,	second cure, verify oven temp, oven calibration	Operator training to MP.	MP designation	Operator training	temp,	second cure, verify oven temp, oven calibration	Train to process steps	Operator training	Cure 1st fill, room temp,	second cure, verily over temp, oven calibration	Operator training to MP.	MP designation	Operator training	CEA procedures	Specification call out/	crean and packaged to protect	Visual inspection	to MP		De-air material as	needed.	Train to process steps	Oven tray design to hold parts horizontal	Oven tray design to hold
ugu dual		Operator Tech	Handling	inadequate flow of fill material	Si not degassed correctly	Stop go and placement technique of needle tip	Temp too high with curing		Cure chamber pressure set incorrectly	Wrong dispensing tip	EFD ressure set incorrectly	inadequate flow of fill material		Si not degassed correctly	Stop go and placement technique of needle tip	Temp too high with curing		Cure chamber pressure set incorrectly	Wrong dispensing tip	EFD pressure set incorrectly	Environment/People	syringe assembly		Lead frame trimming leftovers	Pressure too low	Time too low	Pot life of material ran out		Wrong tip/Clogged tip	Placed into cure oven at an angle - Oven tray design to hold oven not level parts horizontal	Placed into cure oven at an angle
rrenaure device lanue, explant, unintended revision surgery*	Decreased battery life	Potential Process Effect of Failure: > 80% First Pass Yield		Stimulation compromised, unintended or intermittent stimulation			Infection*					Stimulation compromised, unintended or	intermittent stimulation						88	Infection*						Infection*	Tissue damage, irritation		Stimulation compromised, unintended or intermittent etimulation		Backfill more than .03" above Potential Process Effect of Failure; >
bakery file reduced (Due to above 60 C cure)		Epoxy everywhere		Voids or bubbles between conductive elements				was the					exceeding .03" in any direction										-		Backfill more than .01" below Erosion*	header	•				Backfill more than .03" above I
000	3640	3650	3660	3670 Header Fill	3680 1006560	3690	3700		3710	3720	3730	3740		3750	3760	0/		3780	3790	200	3810	3820		3830	140	3850	3860	0200	38/0	00	3890
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Acceptable	Acceptable					Low	Acceptable		Low	Low	Low		Acceptable			Low		Acceptable				Low	Low	Low	Low	Low	ГОМ	Low	Low	Acceptable	Low	Low
9	ω					18		5	7	18	27		4			12		80				18	18	18	18	24	8	12	24	က	12	12
3 2	2 2					3 2		٦,	N	2 3	6	\dashv	2 2			2 2		2 2			-	3 2	3	3	3 2	3	3	3 2	3 2	-	3 2	3
-	2					ю				ო			-			6		2				6	m	6	ო	4	п	2	4	-	2	7
Visual inspection	Automated Dispenser	Visual inspection	Visual inspection	Visual inspection	Visual inspection	Operator training to MP	Operator training to MP,	Visual Inspection	Operator training, visual Inspection	Operator training, Visual	Visual inspection of pins		Cure 1st fill, room temp, second cure, verify oven	temp, oven calibration	Validate cure schedule	Cure 1st fill, room temp,	temp, oven calibration	Tool design/bore inspection	Tool design/bore	inspection	Visual inspection	MP, Training, Equipment Qual	MP, Training, Equipment Qual	MP, Training, Equipment Qual	MP, Training, Equipment Qual	MP, Training, Equipment Qual	MP, Training, Equipment Qual	MP, Training, Equipment	MP, Training, Equipment	MP, Training, Equipment	MP, Training, Equipment	MP, Training, Equipment Qual
Assembly Method	Not enough med6600 in stacker assy	Missing seal	Loss compression on stacker	Not seated stacker assy	Double Seal	epoxy leaks into header area	No MED2000 in anchor slots	Handling	nanumy	lead Handling and Insertion	SR - Burs on pins		Cure temp too low		Cure time too short	Temp Too High		Si Ingress	Damaged Spring		Stacker Augnment	Operator technique, incorrect info loaded	Operator technique, incorrect info loaded	Operator technique, incorrect info loaded	Operator technique, incorrect info loaded	Operator technique, incorrect info loaded	Operator technique, incorrect info loaded	Operator technique, incorrect info	Operator technique, incorrect info	Operator technique, incorrect info	Operator technique, incorrect info	Operator technique, incorrect info loaded
Potential Process Effect of Failure: > 80% First Pass Yield	Electrical leakage		High insertion force, unable to fully insert	lead	Stimulation compromised, unintended or intermittent stimulation	Unable to control stimulation or communicate	Stimulation compromised, unintended or	Internation Summation Premature device failure evolent	unintended revision surgery*	Revision difficulty, unable to remove lead from IPG	Implant difficulty, unable to assemble	system, unable to implant	Potential Process Effect of Failure: > 80% First Pass Yield			Premature device failure, explant, unintended revision surgery*	Decreased battery life	Electrical leakage	High insertion force, unable to fully insert	lead		ō	Stimulation compromised, unintended or intermittent stimulation	Premature device failure, explant, unintended revision surgery*	Unable to recharge	Unable to control stimulation or communicate	Premature device failure, explant, unintended revision surgery*	Premature device failure, explant,	ove 42C)*	Physician inconvenience/dissatisfaction	Premature device failure, explant, unintended revision surgery*	action
SI Ingress in Setscrew	SI Ingress MED6210 - In bore Electrical leakage					cracked header (Leading to tensile issue)				Damaged septum / strain			Sticky Si Material			Battery life reduced (Due to above 60 C cure)		Lead insertion force > 2lbf				5-00-001 Channel leakage not identified	5-00-002 output timing/crosstalk out of tolerance	5-00-003 Telemetry limitations	5-00-004 Charging States incorrectly operating		5-01-005 Active and passive programming error	Frequency control table error	Dynamic Temperature sense	ng incomplete	Overcharged device	Device defective
3900	3910	3920	3930	3940	3950	3960	3970	3980		3990	4000	19	4010		4020	4030	4040	4050 4060	4070	OBOA		4090 Final Electrical Test	4100 1011107	4110	4120	4130	4140	4150	4160	4170 IPG Device Charging	4180 1013904	4190



4200		Device damaged	Potential Process Effect of Failure: 60% Operator technique, incorrect info MP, Training, Equipment	Operator technique, incorrect info	\vdash	2	3 2	12	Low	-		-	H	
4240	A910 Lakel Constration		- 80% First Pass Yield	loaded	Qual	\dashv	\dashv	\downarrow				\dashv	\dashv	\Box
171	Label Generation													
	1013815			Reference 101332;	Reference 1013323 Label Generation PFMEA									
4220	4220 Sterile Packaging 1007791	Retainer adhered to lid	Physician inconvenience/dissatisfaction	inner and retainer tray assembly not completely seated in outer tray	MP	2	2 2	8	Acceptable				<u></u>	
4230	Final Pack		Product damage/sterility compromised									-	-	
4240	1007792	Lid not adhered to outer tray	Physician inconvenience/dissatisfaction	incorrect temp, time, or pressure	MP, PM/Calibration	2	3 2	12	Гом		t	\vdash		
4250			Product damage/sterility compromised	FM on outer tray	blow off prior to use, visual inspection and can rework		2	ω	Acceptable				 	
4260		Low peal strength of lid from	Low peal strength of lid from Product damage/sterility compromised	narrow gasket width	sealing nest TQ, PM	6	2 2	12	Low			H	+	
4270		outer tray		incorrect temp, time, or pressure	MP, PM/Calibration	<u> </u>	3 2	8	Low				-	
4280		"Open here" oriented incorrectly	Physician inconvenience/dissatisfaction	loaded incorrectly	MP, knobs on tray to indicate where "open here" labels should be	-	e E	о	Acceptable				-	
4290		Lid upside down	Potential Process Effect of Failure: > 80% First Pass Yield	loaded incorrectly	MP, single sided adhesive on lid - therefore won't create seal	-	-	-	Acceptable					
4300		IPG loaded into inner tray backwards	Physician inconvenience/dissatisfaction	loaded backwards causing poor it seal	MP, 3x8 model will not fit correctly	-	3 2	φ	Acceptable		ļ	 	\vdash	
4310		Label falls off	not available,	ineffictive label application	MP	2	2 2	80	Acceptable			H	H	
4320			adulterated product	FM on label adhesive	MP, cleanroom practices	<u> </u>	2 2	∞	Acceptable				<u> </u>	
4330		Label not legible	not available,	Ink not dry prior to handling	Laser printing labels?	2	-	2	Acceptable			\vdash	1	
4340			adulterated product	Printer malfunction	visual inspection		3 2	12	Low			\vdash	L	
4350		Label contains wrong variable information	abel contains wrong variable Instructions/labeling not available, aformation	Compt File	MP, QC check	e e	3	18	ГОМ				_	
4360		Shelf box does not contain all contents	Shelf box does not contain all Physician inconvenience/dissatisfaction contents	missed step in loading contents	MP, QC check	-	3	9	Acceptable					
4370		Tear label ripped or damaged	Tear label ripped or damaged Instructions/labeling not available, adulterated product	handling	MP, QC check	2	e e	18	Гом			-		

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