



VIA MED

Microstim MkIII

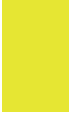
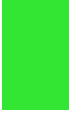
Supramaximal Nerve Stimulator

Class IIa
Via Rule Rule 10
Assesment Route Annex II
NBOG MD 1103

Carried out by Derek Lamb
18 / 04 / 16



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
2500000	Microstim DB3 - PCB Assembly.
2510000	Microstim DB3 - Supramaximal Nerve
2510001	Microstim DB3 - Supramaximal Nerve
2510005	Microstim DB3 Tester
2520000	Microstim DB3 - Patient Lead.
2520001	Microstim DB3 - Patient Lead.
2520003	Microstim DB3 - Patient Lead.
2520020	Microstim DB3 - Patient Lead.
2520021	Microstim DB3 - Patient Lead.
2530001	Microstim DB3 - Upper Case.
2530002	Microstim DB3 - Lower Case.
2530003	Microstim DB3 - Lower Case Label.
2530004	Microstim DB3 - Battery Cover .
2530005	Microstim DB3 - Battery contact +ve.
2530006	Microstim DB3 - Battery contact -ve.
2530007	Microstim DB3 - Cable Battery Contacts
2530008	Microstim DB3 - Case Screw.
2530009	Microstim DB3 - PCB Assembly Screw.
2530010	Microstim DB3 - Output Connector.
2530011	Microstim DB3 - Mode Switch & Bezel.
2530012	Microstim DB3 - Intensity Control Knob.
2530013	Microstim DB3 - Potentiometer.
2530014	Microstim DB3 - Audio Transducer.
2530015	Microstim DB3 - Transistor PSS8050C
2530016	Microstim DB3 - LED
2530017	Microstim DB3 - Label
2530020	Microstim DB3 - PIC Processor
2530021	Microstim DB3 - PIC Processor
2530050	Microstim DB3 - Mode Switch.
2530051	Microstim DB3 - Mode Switch Rocker-Green
2530052	Microstim DB3 - Mode Switch Bezel-Black
2530053	Microstim DB3 - PIC Processor
2530054	Microstim DB3 - PIC Processor
2530060	Microstim DB3 - Crocodile Clip - Red
2530061	Microstim DB3 - Crocodile Clip - Black
2530091	Microstim DB3 - Mode Switch & Bezel.
2550001	Microstim DB3 - Electrode.
2550002	Microstim DB3 - Electrode. Pack of 30.
2550004	Microstim DB3 - Electrode. Box of 300.
2590001	Microstim DB3 - Packaging box.
2590002	Microstim DB3 - Packaging insert tray.
2590010	Microstim DB3 - Leaflet.

Stock Reference	Description
2590012	Microstim DB3 Product Application Shee
2590014	Microstim DB3 - Technical Manual.

Comments on Stock references review:

Parts upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
2530015	Microstim DB3 - Transist	00009023		Electronics Direct	B
2530013	Microstim DB3 - Potentio	00009061	484-8575P	Farnell	A
2530020	Microstim DB3 - PIC Proc	00009061	9760865	Farnell	A
2530052	Microstim DB3 - Mode Swi	00009061	120-1357	Farnell	A
2530013	Microstim DB3 - Potentio	00009123	484-8575P	RS Components Ltd	B
2530060	Microstim DB3 - Crocodil	00009123	483-843	RS Components Ltd	B
2530061	Microstim DB3 - Crocodil	00009123	483-859	RS Components Ltd	B
2520000	Microstim DB3 - Patient	00009132	14C-68660 REV	LHI Technology Ltd	A
2510000	Microstim DB3 - Supramax	00009166		Medu-Scientific Ltd	Needs Grading
2530053	Microstim DB3 - PIC Proc	00009329		Worldlight Engineering L	B
2590010	Microstim DB3 - Leaflet.	00009345	2590010	Duffield Printers	A
2590010	Microstim DB3 - Leaflet.	00009360	2590010	Print Centre	B
2590010	Microstim DB3 - Leaflet.	00009363	2590010	ACI Print Group Impress	B
2550002	Microstim DB3 - Electrode	00009602	KR31.1946.21	Bunzl Healthcare	C
2530017	Microstim DB3 - Label	00010665	2530017	Pendle Signs & Plastics	B
0131352	Oxycal Enclosure	00011450	A9064107	OKW Enclosures	B
2530013	Microstim DB3 - Potentio	00011963	484-8575P	Nobel Electronics Limite	B
2550004	Microstim DB3 - Electrode	00012034	31.1946.21	Covidien (UK) Commercial	B
2500000	Microstim DB3 - PCB Asse	00012164	688-66661	Healthcare Technology In	B
2510000	Microstim DB3 - Supramax	00012164		Healthcare Technology In	B
2520000	Microstim DB3 - Patient	00012164	14C-68660 REV	Healthcare Technology In	B
2520001	Microstim DB3 - Patient	00012164	14C-98881 REV. A	Healthcare Technology In	B
2530001	Microstim DB3 - Upper Ca	00012164	688-66742	Healthcare Technology In	B
2530002	Microstim DB3 - Lower Ca	00012164	688-66743	Healthcare Technology In	B
2530003	Microstim DB3 - Lower Ca	00012164	01L-73422	Healthcare Technology In	B
2530004	Microstim DB3 - Battery	00012164	688-66744	Healthcare Technology In	B
2530005	Microstim DB3 - Battery	00012164	11C-66740	Healthcare Technology In	B
2530006	Microstim DB3 - Battery	00012164	11C-66741	Healthcare Technology In	B
2530007	Microstim DB3 - Cable B	00012164	02W- 73417/73418	Healthcare Technology In	B
2530008	Microstim DB3 - Case Scr	00012164	03S-68702	Healthcare Technology In	B
2530009	Microstim DB3 - PCB Asse	00012164	03S-68701	Healthcare Technology In	B
2530010	Microstim DB3 - Output C	00012164	05P-66693	Healthcare Technology In	B
2530011	Microstim DB3 - Mode Swi	00012164	093-66653	Healthcare Technology In	B
2530012	Microstim DB3 - Intensit	00012164	688-73427	Healthcare Technology In	B
2530014	Microstim DB3 - Audio Tr	00012164	04B-66651	Healthcare Technology In	B
2590001	Microstim DB3 - Packagin	00012164		Healthcare Technology In	B
2590002	Microstim DB3 - Packagin	00012164		Healthcare Technology In	B
2520003	Microstim DB3 - Patient	00012399	2520003	Unimed	B

Comments on Suppliers:

Health care TEchnology is being replaced with a new supplier,

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
2500000	Microstim DB3 - PCB Asse	2		4	4	16	7	
2510000	Microstim DB3 - Supramax	278	388	261	356	504	346	2
2510001	Microstim DB3 - Supramaximal Nerve	78					6	
2510005	Microstim DB3 Tester	4	7	6	15	18	4	5
2520000	Microstim DB3 - Patient	366	443	432	591	520	644	311
2520001	Microstim DB3 - Patient	176	20	162	184	266	57	12
2520003	Microstim DB3 - Patient	48	115	101	36	128	151	31
2520020	Microstim DB3 - Patient Lead.		14	3	3	8	4	1
2520021	Microstim DB3 - Patient Lead.			3				
2530001	Microstim DB3 - Upper Ca			2	2		3	
2530002	Microstim DB3 - Lower Ca	0		2	2		3	
2530003	Microstim DB3 - Lower Ca			7				
2530004	Microstim DB3 - Battery	9	27	12	26	18	35	22
2530005	Microstim DB3 - Battery						153	
2530006	Microstim DB3 - Battery						154	
2530007	Microstim DB3 - Cable B						3	
2530008	Microstim DB3 - Case Scr						12	
2530009	Microstim DB3 - PCB Asse						12	
2530010	Microstim DB3 - Output C		1				123	
2530011	Microstim DB3 - Mode Swi		2	2			132	1
2530012	Microstim DB3 - Intensit	1	27	17	11	53	55	20
2530013	Microstim DB3 - Potentio		4			2	254	2201
2530014	Microstim DB3 - Audio Tr						6	
2530015	Microstim DB3 - Transist						2000	
2530016	Microstim DB3 - LED			2				
2530017	Microstim DB3 - Label							
2530020	Microstim DB3 - PIC Proc						260	2199
2530021	Microstim DB3 - PIC Processor							1
2530050	Microstim DB3 - Mode Switch.					5	1	
2530051	Microstim DB3 - Mode Switch Rocker-Green					4	1	
2530052	Microstim DB3 - Mode Swi					6	1	
2530053	Microstim DB3 - PIC Proc							
2530054	Microstim DB3 - PIC Processor							
2530060	Microstim DB3 - Crocodil							
2530061	Microstim DB3 - Crocodil							
2530091	Microstim DB3 - Mode Switch & Bezel.							
2550001	Microstim DB3 - Electrode.			1				
2550002	Microstim DB3 - Electrod	14	6	5	5	1		
2550004	Microstim DB3 - Electrod				6	19		
2590001	Microstim DB3 - Packagin							
2590002	Microstim DB3 - Packagin							
2590010	Microstim DB3 - Leaflet.		16	2	60	20	40	

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
2590012	Microstim DB3 Product Application Shee							
2590014	Microstim DB3 - Technical Manual.							

Comments on Sales Information:

Supply problems have caused us to have a stock shortage,
customers are aware and being updated regularly

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AUS Australia	[X]	[X]	[X]	[X]	[X]	[X]	[X]
B Belgium	[X]		[X]	[X]	[X]	[X]	[X]
BA State of Bahrain				[X]	[X]		
C China	[X]		[X]	[X]	[X]		
CAN Canada	[X]	[X]	[X]	[X]	[X]	[X]	[X]
CY Cyprus		[X]					
CZ Czech Republic							
DE Denmark							
EG Egypt		[X]		[X]			
F France					[X]		
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	
G Germany			[X]	[X]	[X]	[X]	
GR Greece	[X]	[X]		[X]	[X]	[X]	[X]
HK Hong Kong		[X]				[X]	[X]
I Iran							
IN India				[X]	[X]		
IQ IRAQ				[X]			
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IS Israel				[X]			
J Japan							
KE Kenya		[X]					
KU Kuwait					[X]		
LEB Lebanon							
MA Malaysia	[X]						
MO Morrocco		[X]					
NE Netherlands							
NG Nigera							
NO Norway							
NZ New Zealand			[X]	[X]	[X]	[X]	[X]
OM Oman	[X]			[X]	[X]		
P Poland		[X]	[X]				
PA Pakistan	[X]		[X]			[X]	
PH Philippines			[X]				
PO Portugal							
SA South Africa	[X]	[X]	[X]		[X]	[X]	
SAU Saudi Arabia	[X]	[X]		[X]			
SI Singapore	[X]	[X]	[X]	[X]		[X]	[X]
SP Spain					[X]		
SWI Switzerland	[X]	[X]		[X]	[X]		[X]
SY Syria							
T Turkey							
TUN Tunisia							

Country	2010	2011	2012	2013	2014	2015	2016
UAE U A E	[X]		[X]		[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Still sellingthe units world wide

Comments on Risks with Sales to Countries:

no risks identified with new countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
2510000	Audio transducer replaced			1				
2510000	Battery contacts tightened.							
2510000	Control knob replaced					1	2	
2510000	Control knob spins		1	2				
2510000	Corrosion						1	
2510000	Damaged during transit							
2510000	Dead			3	1	1		1
2510000	Diode replaced							3
2510000	Dry joint	1						1
2510000	False battery low warning					1		
2510000	Faulty patient cable	1				1	1	
2510000	Faulty patient cable replaced	2	5		2	3	1	1
2510000	Intensity knob fitted	2					1	
2510000	Investigate	1						
2510000	Leads replaced	2	2			2		
2510000	LED replaced					1	3	
2510000	Mode switch replaced							1
2510000	Modified to PN:2510001	39						
2510000	No Fault Found	2	4	2	1			1
2510000	No Fault Return to Stock						1	
2510000	No output	3	3	2	2	1		
2510000	PCB assembly replaced	1		1	2	10	14	
2510000	Serviced					1		
2510000	Tested OK	6						
2510000	Unchecked - Returned to Stock							
2510000	Uneconomical to repair, service exchange							
2510005	Unchecked - Returned to Stock							
2520000	No Fault Return to Stock							
2520000	Unchecked - Returned to Stock							
2520003	Unchecked - Returned to Stock							
2530004	No Fault Return to Stock							
2530004	Unchecked - Returned to Stock							
2530012	No Fault Return to Stock							
2530013	No Fault Return to Stock							

Comments on Returns:

Returns are exceptional low.

2016 figures not reflecting true return rate due to supply shortage so percentage returns to sales off the scale,

Comments on Risks with Returns and Potential Re-work:

No risks with returns / reworks

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No product changes, however due to finding a new Key supplier,
and the files are 10-15 years old, its an opportunity to sign off hte files are still valid,

Comments on Risks with Design Changes:

no risks in the design files

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
12210	Microstim MkIII Instructions for Use / User Manual Danish Certif...	29/11/12
12209	Microstim MkIII Instructions for Use / User Manual Danish	29/11/12
12205	Microstim MkIII Instructions for Use / User Manual English	27/11/12
5042	Microstim MkIII Instructions for Use / User Manual French	16/01/09
1059	Microstim Instructions for Use / User Manual Placement Diagram	31/10/06

Comments on User Instructions:

User instructions still upto date,
however with new supplier and new packaging, we will be revisiting the user instructions in light of current legislation (blue man etc)

Comments on Risks User Instructions:

no risks with current instructions,

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9463	Microstim MkIII Labels 250001 Appendix 1 page 20	18/10/11
9462	Microstim MkIII Labels 250001 box label	18/10/11
9169	No accessory labels	18/10/11
4795	Microstim MkIII Labels	20/10/08
4794	Microstim MkIII Labels	20/10/08
4793	Microstim MkIII Labels	20/10/08
4792	Microstim MkIII Labels	20/10/08
3301	Microstim MkIII Labels	26/02/08

Comments on Labels:

As per user instructions.

Comments on Risks Labels:

no risks with current labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16768	Microstim MkIII Clinical Trials Reports Reviews and Post Market ...	18/04/16
16703	Microstim MkIII Test Reports Load vs output	01/04/16
16176	Viamed Certification ISO 13485:2003 MD78787	12/01/16
16169	Microstim MkIII Quality Assurance and Agreements Authorization I...	11/01/16
16041	Microstim MkIII Clinical Trials Reports Reviews and Post Market ...	26/11/15
15941	Microstim MkIII Promotional Leaflet (email)	18/11/15
15894	Microstim MkIII CMDCAS Extra Requirements certificate update	30/10/15
15834	Microstim MkIII Maintenance Test pcb procedure	16/10/15
15833	Microstim MkIII Maintenance test points pcb	16/10/15
15832	Microstim MkIII Maintenance Test points pcb	16/10/15
15831	Microstim MkIII Maintenance Test point pcb	16/10/15
15811	Microstim MkIII Canada Health License Communications	12/10/15
15810	Microstim MkIII Canada Health License Communications yearly upd...	12/10/15
15779	Microstim MkIII Photographs sub assemblies pcb test points	05/10/15
15778	Microstim MkIII Photographs sub assemblys pcb Track side	05/10/15
15775	Microstim MkIII Photographs sub assemblys pcb component side	05/10/15
15722	Microstim MkIII Essential requirements	23/09/15
15628	Microstim MkIII Work Instructions and Tests	10/09/15
15627	Microstim MkIII Service Manual	10/09/15
15602	Microstim MkIII EMC rationale emc testing not possible	08/09/15
15599	2520000 Microstim DB3 - Patient Lead. (2362 / 1795)	07/09/15
15596	Microstim MkIII Clinical Trials Reports Reviews and Post Market ...	07/09/15
15595	Microstim MkIII Clinical Trials Reports Reviews and Post Market ...	07/09/15
15573	BS EN 60601-2-10:2015 Nerve Stimulators	01/09/15
15528	Microstim MkIII Competitors Information and Patients Anaesthesia...	24/08/15
15527	Microstim MkIII Competitors Information and Patients F and P Inn...	24/08/15
15526	Microstim MkIII Competitors Information and Patients F and P Inn...	24/08/15
15425	Microstim MkIII Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15383	Microstim MkIII EC Declaration of Conformance DB3	06/08/15
15381	Microstim MkIII EC Declaration of Conformance 2510001	06/08/15
15380	Microstim MkIII EC Declaration of Conformance 2510000	06/08/15
15301	Microstim MkIII Post Market Clinical Follow-up	30/07/15
15263	Microstim MkIII Drawings HTI Project_688 Elec BOM	27/07/15
15262	Microstim MkIII Drawings HTI Project_688 Top Housing PCB (2)	27/07/15
15261	Microstim MkIII Drawings HTI Project_688 Top Housing PCB (1)	27/07/15
15260	Microstim MkIII Drawings HTI Project_688 PCB	27/07/15
15259	Microstim MkIII Drawings HTI Project_688 ECG Cable	27/07/15
15258	Microstim MkIII Drawings HTI Project_688 Screw Insert	27/07/15
15257	Microstim MkIII Drawings HTI Project_688 Plug and Cable	27/07/15
15256	Microstim MkIII Drawings HTI Project_688 Battery Contact2	27/07/15
15255	Microstim MkIII Drawings HTI Project_688 Battery Contact	27/07/15

Document ID	Description	Date Added/Updated
15254	Microstim MkIII Drawings HTI Project_688 Nut	27/07/15
15253	Microstim MkIII Drawings FOAM	27/07/15
15252	Microstim MkIII Drawings HTI Project_688 Knob base	27/07/15
15251	Microstim MkIII Drawings HTI Project_688 Knob	27/07/15
15250	Microstim MkIII Drawings HTI Project_688 Support Plate	27/07/15
15249	Microstim MkIII Drawings HTI Project_688 Top Housing (4)	27/07/15
15248	Microstim MkIII Drawings HTI Project_688 Battery Cover	27/07/15
15247	Microstim MkIII Drawings HTI Project_688 Top Housing (3)	27/07/15
15246	Microstim MkIII Drawings HTI Project_688 Top Housing (2)	27/07/15
15245	Microstim MkIII Drawings HTI Project_688 Top Housing (1)	27/07/15
15244	Microstim MkIII Drawings HTI Project_688 Bottom Housing (2)	27/07/15
15243	Microstim MkIII Drawings HTI Project_688 Top Housing	27/07/15
15242	Microstim MkIII Drawings HTI Project_688 Bottom Housing (3)	27/07/15
15241	Microstim MkIII Drawings HTI Project_688 Bottom Housing (2)	27/07/15
15240	Microstim MkIII Drawings HTI Project_688 Bottom Housing (1)	27/07/15
15238	Microstim MkIII Drawings HTI Project_688 Bottom Housing (1)	27/07/15
15237	Microstim MkIII Drawings HTI Project_688 Assembly (2)	27/07/15
15236	Microstim MkIII Drawings Microstim MkIII Drawings HTI Project_68...	27/07/15
15235	Microstim MkIII Drawings Microstim MkIII Drawings HTI Project_68...	27/07/15
15234	Microstim MkIII Drawings HTI Project_688 Assembly (1)	27/07/15
15183	No risks disposal	21/07/15
15122	Microstim MkIII Trade Mark Certificate	30/06/15
14574	2510000 MicroStim QA Procedures	24/11/14
14418	Promotional Leaflets Microstim DB3 Version 1.6	03/10/14
13995	Microstim MkIII Risk analysis reports Yearly Post market survea...	30/05/14

Comments on Document Changes:

Lots of new documents flagged, however this is due to find new supplier and a chance to confirm documents are current and upto date
(ms files are very very old + 20years) good chance to check the digital files are correct

Comments on Risks with Document Changes:

no risks with files

Internal Issues Review

Number of Issues reviewed: 348

Issue ID	Subject
5392	
5390	
5389	
5388	
5387	
5386	
5385	
5384	
5383	
5382	
5381	
5380	
5379	
5378	
5377	
5376	
5375	
63471	2510000 - interim update
63470	2510000 - interim update
63469	2510000 - interim update
63468	2510000 - interim update
65844	2510000 - please update the Intrastats memo regarding manufacturing delays
63427	2510000 update
63426	2510000 update
50854	2520000
56766	2520000 Microstim DB3 patient cables
56765	2520000 Microstim DB3 patient cables
56764	2520000 Microstim DB3 patient cables
56763	2520000 Microstim DB3 patient cables
56762	2520000 Microstim DB3 patient cables
56761	2520000 Microstim DB3 patient cables
56760	2520000 Microstim DB3 patient cables
50855	2520003
67745	2530013 stock levels
17458	Are you aware this returned back from sale/return?
68484	Backorder 00000016 2510000 ORD79148
66146	Backorder 00000016 2510005 ORD77947
54744	Backorder 00000020 2510000 ORD71543
60110	Backorder 00000020 2510000 ORD74843
65326	Backorder 00000020 2510000 ORD77456
65780	Backorder 00000020 2510000 ORD77717
57146	Backorder 00000024 2510000 ORD73011

Issue ID	Subject
69073	Backorder 00000030 2510000 ORD79343
63479	Backorder 00000065 2510000 ORD76406
58643	Backorder 00000070 2510000 ORD73960
60090	Backorder 00000070 2510000 ORD74836
64490	Backorder 00000070 2510000 ORD76978
56753	Backorder 00000070 2520000 ORD72735
58703	Backorder 00000075 2510000 ORD73992
60484	Backorder 00000076 2510000 ORD74935
67597	Backorder 00000085 2510000 ORD78774
67201	Backorder 00000085 2520000 ORD78570
63547	Backorder 00000093 2510000 ORD76453
65285	Backorder 00000098 2510000 ORD77431
68679	Backorder 00000110 2510000 ORD79241
54450	Backorder 00000200 2510000 ORD71344
62241	Backorder 00000200 2510000 ORD75823
53123	Backorder 00000280 2510000 ORD70514
64551	Backorder 00000350 2510000 ORD77012
66659	Backorder 00000350 2510005 ORD78199
69913	Backorder 00000390 2530012 ORD79754
63588	Backorder 00000480 2510000 ORD76483
56051	Backorder 00000516 2520000 ORD72369
59223	Backorder 00000580 2520000 ORD74265
64569	Backorder 00000580 2520000 ORD77026
60202	Backorder 00000620 2510000 ORD74888
66610	Backorder 00000620 2510000 ORD78176
69075	Backorder 00000620 2510000 ORD79370
67546	Backorder 00000620 2520000 ORD78743
67383	Backorder 00000620 2530004 ORD78649
68595	Backorder 00000835 2510000 ORD79198
60550	Backorder 00000860 2510000 ORD75017
63141	Backorder 00000860 2530011 ORD76212
63758	Backorder 00000947 2520000 ORD76581
55793	Backorder 00000950 2510000 ORD72055
67598	Backorder 00000950 2510000 ORD78766
54499	Backorder 00000970 2520000 ORD71379
53556	Backorder 00000990 2520000 ORD70856
69401	Backorder 00000990 2520000 ORD79547
52466	Backorder 00001003 2510000 ORD70234
58890	Backorder 00001012 2510000 ORD74112
57840	Backorder 00001040 2510000 ORD73426
66848	Backorder 00001040 2510000 ORD78396
62500	Backorder 00001090 2510000 ORD75949
65755	Backorder 00001090 2510000 ORD77716
66025	Backorder 00001090 2510005 ORD77900
66711	Backorder 00001090 2520000 ORD77900

Issue ID	Subject
69208	Backorder 00001170 2510000 ORD79495
64212	Backorder 00001170 2520000 ORD76866
69101	Backorder 00001170 2520000 ORD79449
64097	Backorder 00001232 2510000 ORD76805
68427	Backorder 00001232 2510000 ORD79124
69985	Backorder 00001232 2510000 ORD79771
58769	Backorder 00001232 2520000 ORD74047
62862	Backorder 00001233 2510000 ORD76090
66154	Backorder 00001310 2520000 ORD77979
57176	Backorder 00001350 2520000 ORD73041
55163	Backorder 00001365 2510000 ORD71740
55162	Backorder 00001365 2520000 ORD71740
55798	Backorder 00001410 2520000 ORD72154
66551	Backorder 00001415 2510000 ORD78160
67633	Backorder 00001420 2510000 ORD78787
54283	Backorder 00001420 2520000 ORD71197
63536	Backorder 00001420 2520000 ORD76437
66634	Backorder 00001420 2520000 ORD78178
55160	Backorder 00001430 2510000 ORD71791
55871	Backorder 00001430 2520000 ORD72219
66609	Backorder 00001500 2510000 ORD78177
69643	Backorder 00001500 2510000 ORD79661
55161	Backorder 00001500 2520000 ORD71720
69402	Backorder 00001500 2520000 ORD79549
55197	Backorder 00001500 2520001 ORD71720
57178	Backorder 00001520 2510000 ORD73039
65337	Backorder 00001550 2520000 ORD77460
67773	Backorder 00001550 2530012 ORD78836
58344	Backorder 00001761 2510000 ORD73763
57115	Backorder 00001780 2510000 ORD72976
61164	Backorder 00001780 2520000 ORD75309
62691	Backorder 00001810 2510000 ORD76035
69002	Backorder 00001850 2510000 ORD79317
59656	Backorder 00001850 2520000 ORD74561
55677	Backorder 00001880 2520000 ORD72048
66844	Backorder 00001902 2510000 ORD78391
69079	Backorder 00001955 2510000 ORD79438
55797	Backorder 00001955 2520001 ORD72145
62160	Backorder 00001965 2510000 ORD75749
65037	Backorder 00002100 2510000 ORD77287
67854	Backorder 00002100 2510000 ORD78875
63954	Backorder 00002100 2520000 ORD76736
55096	Backorder 00002230 2510000 ORD71742
63478	Backorder 00002320 2510000 ORD76405
65651	Backorder 00002340 2520001 ORD77647

Issue ID	Subject
56048	Backorder 00002395 2510000 ORD72367
61295	Backorder 00002420 2510000 ORD75369
67842	Backorder 00002420 2510000 ORD78863
61206	Backorder 00002420 2520000 ORD75347
68194	Backorder 00002420 2520000 ORD79039
55354	Backorder 00002421 2510000 ORD71948
66148	Backorder 00002425 2520000 ORD77971
63966	Backorder 00002500 2510000 ORD76740
65729	Backorder 00002500 2510000 ORD77701
67366	Backorder 00002500 2510000 ORD78637
59274	Backorder 00002570 2510000 ORD74325
69215	Backorder 00002570 2510000 ORD79499
59773	Backorder 00002609 2510000 ORD74629
58765	Backorder 00002690 2520000 ORD74044
66147	Backorder 00002690 2520001 ORD77968
58367	Backorder 00002824 2510000 ORD73783
63526	Backorder 00002824 2510000 ORD76438
68981	Backorder 00003012 2510000 ORD79407
63492	Backorder 00003041 2510000 ORD76403
56898	Backorder 00003450 2510000 ORD72842
53689	Backorder 00003490 2510000 ORD70918
57474	Backorder 00003490 2520000 ORD73268
58040	Backorder 00003500 2510000 ORD73570
61993	Backorder 00003500 2520000 ORD75663
65170	Backorder 00003560 2510000 ORD77354
65449	Backorder 00003560 2510000 ORD77513
60618	Backorder 00003580 2520000 ORD75080
65058	Backorder 00003601 2510000 ORD77299
65728	Backorder 00003601 2510000 ORD77699
65922	Backorder 00003601 2510000 ORD77809
66106	Backorder 00003601 2510000 ORD77935
57260	Backorder 00003601 2520000 ORD73092
68723	Backorder 00003601 2520001 ORD79255
66950	Backorder 00003640 2510000 ORD78465
67307	Backorder 00003640 2510000 ORD78612
68173	Backorder 00003640 2510000 ORD78959
69690	Backorder 00003640 2510000 ORD79672
54604	Backorder 00003665 2520000 ORD71397
64134	Backorder 00003668 2510000 ORD76840
56622	Backorder 00003668 2520000 ORD72605
64071	Backorder 00003785 2510000 ORD76808
65802	Backorder 00003785 2510000 ORD77681
66836	Backorder 00003785 2510000 ORD78388
67976	Backorder 00003785 2510000 ORD78929
68251	Backorder 00003785 2510000 ORD79029

Issue ID	Subject
55741	Backorder 00003892 2520000 ORD72115
58323	Backorder 00003910 2520000 ORD73741
65098	Backorder 00004030 2510000 ORD77317
56701	Backorder 00004040 2510000 ORD72688
68905	Backorder 00004040 2520000 ORD79352
61107	Backorder 00004127 2520003 ORD75267
66116	Backorder 00004128 2510000 ORD77953
57964	Backorder 00004205 2510000 ORD73516
69072	Backorder 00004205 2510000 ORD79341
57550	Backorder 00004260 2510000 ORD73303
69908	Backorder 00004260 2510000 ORD79736
64326	Backorder 00004260 2520000 ORD76921
55277	Backorder 00004260 2520001 ORD71885
55320	Backorder 00004260 2550004 ORD71889
63142	Backorder 00004261 2510000 ORD76178
57967	Backorder 00004282 2510000 ORD73523
68596	Backorder 00004284 2510000 ORD79210
65404	Backorder 00004295 2510000 ORD77503
61163	Backorder 00004300 2530004 ORD75292
63539	Backorder 00004333 2510000 ORD76441
66746	Backorder 00004333 2510000 ORD78275
51512	Backorder 00004400 2510000 ORD69478
55478	Backorder 00004450 2520000 ORD72008
59602	Backorder 00004450 2520000 ORD74506
69912	Backorder 00004450 2520000 ORD79747
63754	Backorder 00004735 2520000 ORD76577
55799	Backorder 00004735 2520001 ORD72150
67596	Backorder 00004974 2510000 ORD78764
63618	Backorder 00005135 2520000 ORD76504
60581	Backorder 00005164 2520000 ORD75037
65861	Backorder 00005169 2510000 ORD77822
67029	Backorder 00005169 2520000 ORD77822
66298	Backorder 00005190 2520000 ORD78045
57224	Backorder 00005256 2510000 ORD73056
67853	Backorder 00005380 2500000 ORD78865
65946	Backorder 00005380 2510000 ORD77875
67986	Backorder 00005380 2530021 ORD78865
65561	Backorder 00005395 2510000 ORD77586
56595	Backorder 00005430 2510000 ORD72599
66379	Backorder 00005445 2520000 ORD78054
68390	Backorder 00005445 2520000 ORD79111
66280	Backorder 00005520 2510000 ORD78025
58710	Backorder 00005520 2520000 ORD74003
65947	Backorder 00005520 2520000 ORD77878
50387	Backorder 00006039 2510000 ORD68467

Issue ID	Subject
51942	Backorder 00006039 2510000 ORD69700
54300	Backorder 00006039 2510000 ORD71175
59505	Backorder 00006039 2510000 ORD74472
63487	Backorder 00006039 2510000 ORD76409
66061	Backorder 00006039 2510000 ORD77921
68802	Backorder 00006039 2520000 ORD79299
56129	Backorder 00006240 2520020 ORD72398
69396	Backorder 00006323 2530013 ORD79546
52098	Backorder 00007016 2510000 ORD69992
54386	Backorder 00007016 2510000 ORD71277
65162	Backorder 00007016 2510000 ORD77349
66606	Backorder 00007020 2510000 ORD77976
66706	Backorder 00007020 2510005 ORD77976
67595	Backorder 00007088 2510000 ORD78763
53548	Backorder 00007359 2510000 ORD70844
58357	Backorder 00007359 2510000 ORD73745
62279	Backorder 00007359 2510000 ORD75859
63661	Backorder 00007359 2510000 ORD76524
68485	Backorder 00007359 2510000 ORD79157
56952	Backorder 00007359 2510001 ORD72871
60331	Backorder 00007359 2510001 ORD74897
68264	Backorder 00007359 2520000 ORD79064
54911	Backorder 00007359 2530050 ORD71646
54196	Backorder 00007374 2510000 ORD71139
65603	Backorder 00007374 2510000 ORD77599
55924	Backorder 00007374 2520000 ORD72272
57156	Backorder 00007446 2510000 ORD73016
62467	Backorder 00007528 2510000 ORD75934
66998	Backorder 00007528 2510000 ORD78494
55260	Backorder 00007528 2520000 ORD71826
68329	Backorder 00007528 2520000 ORD78494
69210	Backorder 00007528 2520000 ORD79477
61697	Backorder 00007530 2510000 ORD75495
55810	Backorder 00007530 2520000 ORD72148
64709	Backorder 00007530 2520000 ORD77084
57437	Backorder 00007586 2510000 ORD73237
63463	Backorder 00007586 2510000 ORD76351
63978	Backorder 00007586 2510000 ORD76735
64225	Backorder 00007586 2510000 ORD76869
64874	Backorder 00007586 2510000 ORD77164
65119	Backorder 00007586 2510000 ORD77324
67973	Backorder 00007586 2510000 ORD78919
69001	Backorder 00007586 2510000 ORD79350
54666	Backorder 00007945 2510000 ORD71516
57935	Backorder 00007945 2510000 ORD73511

Issue ID	Subject
59820	Backorder 00007945 2510000 ORD74662
69579	Backorder 00007945 2510000 ORD79625
68256	Backorder 00007945 2520000 ORD79053
50786	Backorder 00007976 2510000 ORD68969
66023	Backorder 00007983 2510000 ORD77905
66151	Backorder 00009127 2520000 ORD77977
58319	Backorder 00011715 2510000 ORD73739
63774	Backorder 00011982 2510000 ORD76599
66499	Backorder 00011982 2510000 ORD78096
53499	Backorder 00011982 2520020 ORD70795
64407	Backorder 00011982 2520020 ORD76599
69074	Backorder 00012163 2510000 ORD79348
54743	Backorder 00012178 2510000 ORD71542
56024	Backorder 00012178 2510000 ORD72351
65974	Backorder 00012178 2510000 ORD77892
55133	Backorder 00012178 2520000 ORD71756
53501	Backorder 00012213 2520020 ORD70749
61037	Backorder 00012438 2510000 ORD75223
66888	Backorder 00012492 2510005 ORD78420
60926	Backorder 00012605 2520000 ORD75168
60927	Backorder 00012605 2530006 ORD75168
57320	Backorder 00012698 2520000 ORD73134
67346	Backorder 00012953 2520020 ORD78635
50478	Country of Origin
66375	DB3 components datasheets
61145	DB3 Production Project 2015
66382	DB3 Technical File - 2530010
14817	DB3 tester kit.
14851	DB3 Tester Pricing
54444	Document Update Request
62016	Double burst stimulation waveform pattern
64028	Error on QA data pages
57401	GHX Brands
61686	Letter to Dyna Medical Regarding Sales Projections for the Microstim
61685	Letter to Dyna Medical Regarding Sales Projections for the Microstim
58871	Lincoln County Hospital
58256	Literature/samples
58255	Literature/samples
49427	Mailshot - Microstim, EBME, April 2014
49428	Mailshot - Microstim, Operating Theatres, April 2014
51578	Microstim - suggested future features (update)
59792	Microstim back Lbl
65918	Microstim componets to ship to Medu-Scientific
51275	Microstim DB3 - ordering of 3rd batch
51274	Microstim DB3 - ordering of 3rd batch

Issue ID	Subject
51273	Microstim DB3 - ordering of 3rd batch
51272	Microstim DB3 - ordering of 3rd batch
51271	Microstim DB3 - ordering of 3rd batch
51563	Microstim DB3 2510000
51562	Microstim DB3 2510000
66376	Microstim DB3 tooling costs
62551	Microstim DBIII M3 Specification
65888	Microstim leads failing
65887	Microstim leads failing
56286	Microstim Leaflets
56285	Microstim Leaflets
69483	Microstim Output
61147	Microstim samples to ship
69539	need a way of reporting errors on orders that people other than the office put on
14963	Order number received?
56835	Part numbers and prices required for 2510001
56834	Part numbers and prices required for 2510001
45229	PETO/GHX Export - Requires sending
60877	Request Scanning Item to Sale or return
59421	Request Scanning Item to Sale or return
56613	Request Scanning Item to Sale or return
56612	Request Scanning Item to Sale or return
55851	Request Scanning Item to Sale or return
54446	Request Scanning Item to Sale or return
59856	Returned Items SOR619
57841	Returned Items SOR629
60497	Returned Items SOR656
57855	Sale or return giving
51535	Sales literature
51534	Sales literature
52274	Southend University Hosp
67264	Stock View - Back Orders
65807	Urgent - Microstim potentiometers to order
54274	Urgent Order
54273	Urgent Order
54272	Urgent Order

Comments on Issues:

Many customer issues on lead time due to finding new supplier

Comments on Risks with Issues:

No risks identified

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Search for clinical usage of supramaximal nerve stimulator in anesthesia

Kinemyography reference was found as a new technique - too soon to determine if it will superceed the
Super maximal nerve stimultor.

See DocID#16768

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

returned results for vagus nerve stimulators, but not Super maximal nerve stimultor.

no fda reports found