



VIA MED

V1000 Foetal Heart Simulator



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
0013110	Carrying case.
1410000	Foetal Heart Simulator model V1000.
1420000	Wall mount for Foetal Heart Simulator
1420001	Case protector for Foetal Heart
1430270	PCB - Foetal Heart Simulator.
1430284	V1000 Case with keypad cut outs.
1430285	V1000 Case.
1430286	V1000 Case Seal Kit.
1430287	V1000 Battery Compartment 4 x AA
1430288	V1000 Battery Clip 4 x AA
1430295	V1000 Keypad Membrane
1430296	V1000 label set (2) - case rear panel.
1430297	V1000 intensity control potentiometer.
1430300	V1000 PCB Assembly.
1430301	V1000 Transducer Mount.
1430302	V1000 Transducer.
1430303	V1000 Transducer mounting screw.
1430304	V1000 Transducer mounting washer.
1430305	V1000 Transducer mounting nut/spacer.
1430306	V1000 Transducer screw.
1430307	V1000 Transducer washer.
1430308	V1000 Transducer nut.
1430309	V1000 Transducer interface cushion.
1430319	V1000 Transducer interface cushion (v2).
1430320	V1000 Transducer v2.
1440000	Labour charge - Repair of V1000 Foetal
1450000	Packing box - V1000
1480000	Foetal Heart Simulator V1000 - Service
1480001	Foetal Heart Simulator V1000 -
1490000	Leaflet - V1000 Foetal heart simulator.
1490001	Instructions for Use - V1000 Foetal
1490002	V1000 Product Application Sheet

Comments on Stock references review:

part numbers upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
1430297	V1000 intensity control	00009061	790-4401	Farnell	A
1430303	V1000 Transducer mountin	00009061	142-0528	Farnell	A
1430304	V1000 Transducer mountin	00009061	162-3987	Farnell	A
1430305	V1000 Transducer mountin	00009061	141-9449	Farnell	A
1430297	V1000 intensity control	00009123	790-4401	RS Components Ltd	A
1430320	V1000 Transducer v2.	00009123	786-8929	RS Components Ltd	A
1430306	V1000 Transducer screw.	00009314	0721020008Z	Bradford Bolt & Nut Comp	B
1430307	V1000 Transducer washer.	00009314	211M020AZ	Bradford Bolt & Nut Comp	B
1430308	V1000 Transducer nut.	00009314	0911020Z	Bradford Bolt & Nut Comp	B
1490000	Leaflet - V1000 Foetal h	00009360		Print Centre	B
1490000	Leaflet - V1000 Foetal h	00009366		Warwick Printing	B
1490001	Instructions for Use - V	00009366		Warwick Printing	B
0013110	Carrying case.	00009445		Openhouse Products Ltd	B
1430270	PCB - Foetal Heart Simul	00010020		P & M Services	B
1430284	V1000 Case with keypad	00010665		Pendle Signs & Plastics	B
1430296	V1000 label set (2) - ca	00010665	1430296	Pendle Signs & Plastics	B
1420000	Wall mount for Foetal He	00011450	A 92 26 227	OKW Enclosures	B
1420001	Case protector for Foeta	00011450	A9177008	OKW Enclosures	B
1430285	V1000 Case.	00011450	A9077107	OKW Enclosures	B
1430286	V1000 Case Seal Kit.	00011450	A9177006	OKW Enclosures	B
1430287	V1000 Battery Compartment	00011450	A9174004	OKW Enclosures	B
1430288	V1000 Battery Clip 4 x A	00011450	A9161001	OKW Enclosures	B
1450000	Packing box - V1000	00011818	4703	Macfarlane Group	B
1430300	V1000 PCB Assembly.	00012189	V1000-1.1	Northern Hi-Tec - NHT	B
1430301	V1000 Transducer Mount.	00012189	V1000-2	Northern Hi-Tec - NHT	B
1430295	V1000 Keypad Membrane	00012225		Danielson - Schurter	B
1430302	V1000 Transducer.	00012227	WM-R57A	Omni Circuits Internatio	B

Comments on Suppliers:

all supplier reviews upto date with regard the V1000

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0013110	Carrying case.	16	10	5	11	9	6	2
1410000	Foetal Heart Simulator model V1000.	26	24	17	34	38	43	14
1420000	Wall mount for Foetal He		1	1			2	1
1420001	Case protector for Foeta	6	7	3	7	9	24	3
1430270	PCB - Foetal Heart Simul							
1430284	V1000 Case with keypad							
1430285	V1000 Case.							
1430286	V1000 Case Seal Kit.							
1430287	V1000 Battery Compartment							
1430288	V1000 Battery Clip 4 x A	1				1	1	
1430295	V1000 Keypad Membrane	3	3	3	7	3	10	4
1430296	V1000 label set (2) - ca							
1430297	V1000 intensity control				1		1	
1430300	V1000 PCB Assembly.		1			1	1	
1430301	V1000 Transducer Mount.					2		1
1430302	V1000 Transducer.							
1430303	V1000 Transducer mountin							
1430304	V1000 Transducer mountin							
1430305	V1000 Transducer mountin							
1430306	V1000 Transducer screw.							4
1430307	V1000 Transducer washer.							4
1430308	V1000 Transducer nut.							8
1430309	V1000 Transducer interface cushion.	59	18	7	11	19	40	14
1430319	V1000 Transducer interface cushion (v2).	3	1	19	6	6		
1430320	V1000 Transducer v2.					2		1
1440000	Labour charge - Repair of V1000 Foetal							
1450000	Packing box - V1000							
1480000	Foetal Heart Simulator V1000 - Service	57	21	22	17	22	44	15
1480001	Foetal Heart Simulator V1000 -							
1490000	Leaflet - V1000 Foetal h			10				
1490001	Instructions for Use - V							
1490002	V1000 Product Application Sheet							

Comments on Sales Information:

units still selling in limited numbers

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
AU Austria							[X]
AUS Australia	[X]	[X]		[X]			
B Belgium						[X]	
C China				[X]		[X]	
CH Chile		[X]					
CO Colombia				[X]	[X]	[X]	[X]
CZ Czech Republic	[X]						
DE Denmark	[X]						
F France	[X]	[X]	[X]	[X]		[X]	[X]
FI Finland		[X]					
G Germany	[X]	[X]	[X]		[X]	[X]	[X]
GR Greece							
HK Hong Kong				[X]		[X]	
HU Hungary						[X]	
I Iran							
IN India	[X]	[X]	[X]		[X]	[X]	
IND Indonesia	[X]	[X]					[X]
IQ IRAQ			[X]				
IRE Ireland		[X]	[X]	[X]	[X]	[X]	[X]
IT Italy			[X]				
MA Malaysia		[X]			[X]	[X]	
NE Netherlands		[X]	[X]			[X]	
NO Norway				[X]	[X]		
NZ New Zealand							
OM Oman					[X]		
P Poland							
PA Pakistan						[X]	
PE Peru					[X]		
PH Philippines				[X]			[X]
PO Portugal	[X]						
RO Romania							
RU Russia							
SA South Africa	[X]		[X]	[X]	[X]	[X]	
SAU Saudi Arabia							
SER Serbia						[X]	
SI Singapore						[X]	
SP Spain							[X]
SWI Switzerland							
TH Thailand			[X]				
UAE U A E		[X]		[X]	[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA			[X]	[X]	[X]		

Comments on Sales to Countries:

wide range of countries sold to

Comments on Risks with Sales to Countries:

no risks using the v1000 in countries

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0013110	No Fault Found					1		
0013110	No Fault Return to Stock							
1410000	Battery contacts replaced and calibrated					1	1	
1410000	Broken wire				1			
1410000	Clean and check					3	1	
1410000	Dead	1				1		
1410000	Faulty board				1			
1410000	Membrane keys not working		1		1	2		
1410000	New	1	1					
1410000	No Fault Found				1	1		
1410000	Replaced interface cushion							1
1410000	Replaced keyboard interface cushion	2	1	5	5	3		
1410000	Replaced Keypad						2	
1410000	Replaced PCB and calibrate					1	1	
1410000	Replaced Potentiometer						1	
1410000	Replaced transducer and serviced							2
1410000	Replaced transducer interface cushion and calibrate	21	22	17	10	12	12	3
1410000	Serviced and calibrated				1	5	20	7
1410000	Serviced with new Keypad						6	4
1410000	Serviced with new pot and keypad				1			
1410000	Transducer cushion interface replaced.		1			1		
1410000	Unchecked - Returned to Stock							
1410000	Unit leaking							
1420001	Needs Evaluating							
1420001	No Fault Found					1		
1420001	Unchecked - Returned to Stock	1						

Comments on Returns:

transducer replacements in PM servicing
limited number keypad failures, all out of warranty period

Comments on Risks with Returns and Potential Re-work:

no risks with servicing / returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no document changes

Comments on Risks with Design Changes:

n/a

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
16897	V1000 Foetal Heart Simulator Instructions for Use User Manual	10/05/16

Comments on User Instructions:

IFU pretty up,

Comments on Risks User Instructions:

no risks with IFU

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
12017	V1000 Foetal Heart Simulator Labels	11/10/12

Comments on Labels:

no changes to labels

Comments on Risks Labels:

no risks with labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
19475	V1000 Foetal Heart Simulator Sub assemblies and Circuit diagrams...	30/03/17
19473	V1000 Foetal Heart Simulator Sub assemblies and Circuit diagrams...	30/03/17
19471	V1000 Foetal Heart Simulator Sub assemblies and Circuit diagrams...	30/03/17
17241	V1000 Foetal Heart Simulator Leaflet (high)	27/07/16
16897	V1000 Foetal Heart Simulator Instructions for Use User Manual	10/05/16
16787	V1000 Foetal Heart Simulator Clinical Trials Reports Reviews and...	20/04/16

Comments on Document Changes:

added old pcb files from the old software used to produce them
file format unable to be opened on site however we have confirmed they are still valid file types and used in
PCB manufactuer

Comments on Risks with Document Changes:

no risks with new documents

Internal Issues Review

Number of Issues reviewed: 59

Issue ID	Subject
72630	Backorder 00001770 1410000 ORD80700
91815	Backorder 00003000 1410000 ORD85576
74430	Backorder 00003912 1430309 ORD81142
69911	Backorder 00004300 1410000 ORD79761
76929	Backorder 00004735 1410000 ORD81818
70298	Backorder 00005320 1410000 ORD79852
82141	Backorder 00006070 1410000 ORD82974
76553	Backorder 00006124 0013110 ORD81784
77360	Backorder 00006124 1410000 ORD81784
84150	Backorder 00006124 1410000 ORD83553
78244	Backorder 00006381 1410000 ORD82084
81837	Backorder 00006386 1410000 ORD82893
86124	Backorder 00006400 1410000 ORD84132
86130	Backorder 00006710 1410000 ORD83978
85988	Backorder 00006710 1420000 ORD83978
71995	Backorder 00007218 1410000 ORD80437
93647	Backorder 00007218 1410000 ORD86049
84703	Backorder 00007453 1480000 ORD83683
76930	Backorder 00007545 1410000 ORD81825
73259	Backorder 00007909 1410000 ORD80908
86515	Backorder 00007909 1410000 ORD84176
91696	Backorder 00007909 1410000 ORD85545
78362	DOCID 17365
64476	Document Update Request (11953)
78281	Document Update Request (17365)
91125	Is this Possible?
71512	POR10719 1430320 //
70862	POR10719 1430320 //
70554	POR10719 1430320 //
71523	POR10719 1430320 16/06/2016
74919	POR10719 1430320 29/07/2016
70549	POR10720 1430303 //
70550	POR10720 1430304 //
70551	POR10720 1430305 //
71252	POR10735 1490001 //
74326	POR10819 1490000 //
74717	POR10819 1490000 07/07/2016
79011	POR10905 0013110 //
79008	POR10905 0013110 //
77881	POR10905 0013110 //
80480	POR10972 1490000 //
86843	POR11097 1420000 //

Issue ID	Subject
86842	POR11097 1420000 //
86427	POR11097 1420000 //
86148	POR11097 1420000 //
88047	POR11131 1430320 //
87772	POR11131 1430320 //
88396	POR11131 1430320 21/03/2017
88149	POR11142 1430308 //
75136	Proforma for 3 x V1000
81737	Request Scanning Item to Sale or return
77678	Request Scanning Item to Sale or return
83776	Returned Items SOR745
93168	SRS65920 V100 repairs processing issues
58664	V1000 1410000 keypad
68130	V1000 cases 1430284
61931	V1000 Declaration of Conformity
72913	V1000 Outer Box Label
93427	Web Site Question ID 1036

Comments on Issues:

mainly sales issues in the system

Comments on Risks with Issues:

no risks found in the issues system

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 :

n/a test equipment, not for clinical use

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 :

n/a test equipment, not for clinical use, but no fda reports found