



V1000 Foetal Heart Simulator

Class I

Carried out by Derek Lamb
24 / 07 / 19



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

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	114-1620	Farnell	B
1430303	V1000 Transducer mountin	00009061	142-0528	Farnell	B
1430304	V1000 Transducer mountin	00009061	162-3987	Farnell	B
1430305	V1000 Transducer mountin	00009061	141-9449	Farnell	B
1430297	V1000 intensity control	00009123	114-1620	RS Components Ltd	B
1430320	V1000 Transducer v2.	00009123	786-8929	RS Components Ltd	B
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	C
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 Compartmen	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:

supplier reviews are upto date

Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
0013110	Carrying case.	5	11	9	6	5	3	2
1410000	Foetal Heart Simulator model V1000.	17	34	38	43	34	53	18
1420000	Wall mount for Foetal He	1			2	5	1	1
1420001	Case protector for Foeta	3	7	9	24	12	24	2
1430270	PCB - Foetal Heart Simul							
1430284	V1000 Case with keypad					1		
1430285	V1000 Case.						100	
1430286	V1000 Case Seal Kit.							
1430287	V1000 Battery Compartmen							
1430288	V1000 Battery Clip 4 x A			1	1	1	1	
1430295	V1000 Keypad Membrane	3	7	3	9	15	4	3
1430296	V1000 label set (2) - ca							
1430297	V1000 intensity control		1		1	2		
1430300	V1000 PCB Assembly.			1	1			1
1430301	V1000 Transducer Mount.			2		1		
1430302	V1000 Transducer.						1	1
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.	7	11	19	39	36	38	11
1430319	V1000 Transducer interface cushion (v2).	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	22	17	22	43	36	38	13
1480001	Foetal Heart Simulator V1000 -					8	10	8
1490000	Leaflet - V1000 Foetal h	10					50	
1490001	Instructions for Use - V							
1490002	V1000 Product Application Sheet							

Comments on Sales Information:

units and parts still selling

Countries Review

Country	2013	2014	2015	2016	2017	2018	2019
AU Austria					[X]	[X]	
AUS Australia		[X]					
B Belgium			[X]			[X]	
BA Kingdom of Bahrain					[X]		
C China		[X]		[X]	[X]	[X]	
CH Chile						[X]	
CO Colombia		[X]	[X]	[X]	[X]	[X]	[X]
CZ Czech Republic						[X]	
DE Denmark					[X]		
F France	[X]	[X]		[X]	[X]	[X]	[X]
FI Finland							
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]	[X]
IND Indonesia					[X]	[X]	[X]
IQ IRAQ	[X]						
IRE Ireland	[X]						
IT Italy	[X]						
J Japan						[X]	
LIB Libya						[X]	
MA Malaysia			[X]	[X]		[X]	[X]
NE Netherlands	[X]			[X]			
NI Northern Ireland							
NO Norway		[X]	[X]				
NZ New Zealand							
OM Oman			[X]		[X]		
P Poland							
PA Pakistan				[X]	[X]	[X]	
PE Peru			[X]				
PH Philippines		[X]			[X]		
PO Portugal					[X]		[X]
RO Romania					[X]	[X]	
RU Russia							
SA South Africa	[X]	[X]	[X]	[X]	[X]		
SAU Saudi Arabia							
SC Scotland			[X]	[X]	[X]	[X]	[X]
SER Serbia				[X]		[X]	
SI Singapore				[X]		[X]	
SP Spain					[X]	[X]	

Country	2013	2014	2015	2016	2017	2018	2019
SWI Switzerland							
TH Thailand	[X]						
UAE U A E		[X]	[X]		[X]		
UK United Kingdom	[X]						
USA USA	[X]	[X]	[X]		[X]	[X]	[X]

Comments on Sales to Countries:

units have been sold world wide for roughly 16 years without incident

Comments on Risks with Sales to Countries:

no risks identified

Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
0013110	No Fault Found			1				
0013110	No Fault Return To Stock							
1410000	Battery Contacts Replaced And Calibrated			1	1		1	
1410000	Broken Wire		1				1	
1410000	Calibration Checked					6	9	8
1410000	Clean And Check			3	1			
1410000	Dead			1				
1410000	Faulty Board		1					
1410000	Membrane Keys Not Working		1	2				
1410000	New						1	2
1410000	No Fault Found		1	1		1		3
1410000	Replaced Interface Cushion					1		
1410000	Replaced Keyboard Interface Cushion	5	5	3		2		
1410000	Replaced Keypad				2	4		
1410000	Replaced Keypad And Checked Calibration					5	4	2
1410000	Replaced PCB And Calibrate			1	1			
1410000	Replaced PCB and Keypad then Calibrate							1
1410000	Replaced Potentiometer				1			
1410000	Replaced Transducer And Serviced					2	1	1
1410000	Replaced Transducer Interface Cushion And Calibrate	17	10	12	12	4		
1410000	Serviced And Calibrated		1	5	20	9		
1410000	Serviced And Calibration Checked					11	33	11
1410000	Serviced With New Keypad				6	5		
1410000	Serviced With New Pot And Keypad		1					
1410000	Transducer Cushion Interface Replaced.			1				
1410000	Unchecked - Returned To Stock							
1410000	Unit Leaking							
1420001	No Fault Found			1				
1420001	No Fault Return To Stock					1		
1420001	Unchecked - Returned To Stock							

Comments on Returns:

mainly returns are services and calibration checks.
a limited number of keypad issues.

Comments on Risks with Returns and Potential Re-work:

no risks with returns
keypad issue limited and results in device failure, but no risk to machine being tested

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

no risks identified

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 V1...	10/05/16

Comments on User Instructions:

no changes to ifu

Comments on Risks User Instructions:

no risks identified

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 labelling

Comments on Risks Labels:

no risks identified

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
30337	V1000 Foetal Heart Simulator EC Declaration of Conformance	16/07/19
28056	V1000 Foetal Heart Simulator Leaflet (high)	30/10/18
27570	V1000 Foetal Heart Simulator Miscellaneous non essential backgro...	27/09/18
27568	V1000 Foetal Heart Simulator Background notes use of V1000 use o...	27/09/18
27102	V1000 Foetal Heart Simulator Circuit Diagrams V1000 Circuit MkII	29/08/18
26427	V1000 Foetal Heart Simulator Clinical Trials Reports Reviews and...	13/06/18

Comments on Document Changes:

added background notes to tech files, no real document changes

Comments on Risks with Document Changes:

no risks identified with document changes

Internal Issues Review

Number of Issues reviewed: 78

Issue ID	Subject
128231	Office Meeting Sales Back Orders Review - By Customer Backorder 00000550 1410000 ORD94099
137747	Office Meeting Sales Back Orders Review - By Customer Backorder 00000570 1410000 ORD96535
130856	Office Meeting Sales Back Orders Review - By Customer Backorder 00001365 1410000 ORD94735
127932	Office Meeting Sales Back Orders Review - By Customer Backorder 00001770 1430309 ORD94060
127514	Office Meeting Sales Back Orders Review - By Customer Backorder 00002191 1480001 ORD93962
137733	Office Meeting Sales Back Orders Review - By Customer Backorder 00002191 1480001 ORD96524
147834	Office Meeting Sales Back Orders Review - By Customer Backorder 00002380 1410000 ORD98673
148561	Office Meeting Sales Back Orders Review - By Customer Backorder 00002380 1410000 ORD98825
127949	Office Meeting Sales Back Orders Review - By Customer Backorder 00003836 1430288 ORD94077
149986	Office Meeting Sales Back Orders Review - By Customer Backorder 00003880 1410000 ORD99133
137725	Office Meeting Sales Back Orders Review - By Customer Backorder 00004127 1410000 ORD96521
123807	Office Meeting Sales Back Orders Review - By Customer Backorder 00004670 1410000 ORD93031
116010	Office Meeting Sales Back Orders Review - By Customer Backorder 00005210 1410000 ORD91139
116005	Office Meeting Sales Back Orders Review - By Customer Backorder 00006388 1410000 ORD91134
116442	Office Meeting Sales Back Orders Review - By Customer Backorder 00006454 1410000 ORD91239
143494	Office Meeting Sales Back Orders Review - By Customer Backorder 00006454 1410000 ORD97821
128193	Office Meeting Sales Back Orders Review - By Customer Backorder 00006523 1410000 ORD94092
140309	Office Meeting Sales Back Orders Review - By Customer Backorder 00006559 1410000 ORD97116
146448	Office Meeting Sales Back Orders Review - By Customer Backorder 00006562 1410000 ORD98387
146445	Office Meeting Sales Back Orders Review - By Customer Backorder 00006571 1410000 ORD98353
115746	Office Meeting Sales Back Orders Review - By Customer Backorder 00006727 1410000 ORD91073
133061	Office Meeting Sales Back Orders Review - By Customer Backorder 00007218 1410000 ORD95343
133281	Office Meeting Sales Back Orders Review - By Customer Backorder 00007518 1430309 ORD95274
138568	Office Meeting Sales Back Orders Review - By Customer Backorder 00007909 0013110 ORD96721

Issue ID	Subject
129985	Office Meeting Sales Back Orders Review - By Customer Backorder 00007909 1410000 ORD94495
128025	Office Meeting Sales Back Orders Review - By Customer Backorder 00011608 1410000 ORD94086
149652	Office Meeting Post Market Surveillance File 66 V1000 Foetal Heart Simulator Risk File Updated
136252	Office Meeting Stock Queries Need a stock check,
124533	Office Meeting Computer Maintenance New Email address: For servicing
143740	Office Meeting VIAMED Stock Meeting Production In Production List (556)
139390	Office Meeting VIAMED Stock Meeting Production In Production List (556)
137345	Office Meeting VIAMED Stock Meeting Production In Production List (556)
127518	Office Meeting Other Repair codes V1000
134718	Office Meeting Sale or Returns Request Scanning Item to Sale or return
127347	Office Meeting Sale or Returns Request Scanning Item to Sale or return
122612	Office Meeting Sale or Returns Request Scanning Item to Sale or return
137668	Office Meeting Sale or Returns Request Scanning Item to Sale or return - SOR896
126478	Office Meeting Sale or Returns Returned Items SOR857
128258	Office Meeting Sale or Returns Returned Items SOR877
137744	Office Meeting Sale or Returns Returned Items SOR892
139326	Office Meeting Sale or Returns Returned Items SOR896
144824	Office Meeting Sale or Returns Returned Items SOR900
140318	Office Meeting Sale or Returns Sale Return SOR900 Princess Alexandra Hospital
125772	Office Meeting VIAMED Sales And Marketing Send Service Offers (607)
124534	Office Meeting Instrastats Serviceable Items: Clear
125306	Office Meeting Marketing Job Logger Servicing Letters - V1000 and Tom Thumb
125305	Office Meeting Marketing Job Logger Servicing Letters - V1000 and Tom Thumb
125304	Office Meeting Marketing Job Logger Servicing Letters - V1000 and Tom Thumb
124541	Office Meeting Marketing Job Logger Servicing Letters - V1000 and Tom Thumb
129827	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing

Issue ID	Subject
129826	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing
129825	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing
129824	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing
129823	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing
129822	Office Meeting Existing Good Products V1000 Certificate of Calibration and Servicing
100588	Office Meeting Product Feedback Negative V1000 failures - needs a response
123898	Office Meeting Any other business V1000 FAQ aditions
123897	Office Meeting Any other business V1000 FAQ aditions
123896	Office Meeting Any other business V1000 FAQ aditions
123895	Office Meeting Any other business V1000 FAQ aditions
123894	Office Meeting Any other business V1000 FAQ aditions
123893	Office Meeting Any other business V1000 FAQ aditions
123892	Office Meeting Any other business V1000 FAQ aditions
123891	Office Meeting Any other business V1000 FAQ aditions
123890	Office Meeting Any other business V1000 FAQ aditions
123889	Office Meeting Any other business V1000 FAQ aditions
123888	Office Meeting Any other business V1000 FAQ aditions
123887	Office Meeting Any other business V1000 FAQ aditions
96591	Office Meeting Any Other Business V1000 keypad fault
128263	Office Meeting Mailshots UK V1000 Servicing Options Letter V2
126418	Office Meeting Web Site Updates Web Site Question ID 1227
132918	Office Meeting Web Site Updates Web Site Question ID 1278
132921	Office Meeting Web Site Updates Web Site Question ID 1279
136865	Office Meeting Web Site Updates Web Site Question ID 1302
139538	Office Meeting Web Site Updates Web Site Question ID 1312
140079	Office Meeting Web Site Updates Web Site Question ID 1317

Issue ID	Subject
147315	Office Meeting Web Site Updates Web Site Question ID 7790
147424	Office Meeting Web Site Updates Web Site Question ID 7791

Comments on Issues:

96591 VIAMED Stock Meeting Any Other Business Any Other Business
keypad issue, and supplier change its process to produce as per original design
so not a design change as such

Comments on Risks with Issues:

no risks identified in the issue system

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000550 1410000 ORD94099

Issue ID #128231

Date Created 18/Sep/2018

Issued To: General

Completed Status: 19 Sep 2018

Stock Ref: 1410000

Opera A/c: 00000550

Order Number: ORD94099

Notes:

18 Sep 2018 12:54:38 PM Sarah Walton

See Attached Notes

This has now been taken off hold and okay to be invoiced.

Issues:128231

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000570 1410000 ORD96535

Issue ID #137747

Date Created 07/Feb/2019

Issued To: General

Completed Status: 08 Feb 2019

Stock Ref: 1410000

Opera A/c: 00000570

Order Number: ORD96535

Notes:

07 Feb 2019 10:24:20 AM Zoey Teal
Carriage charge accepted. OK to ship.

Issues:137747

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001365 1410000 ORD94735

Issue ID #130856

Date Created 24/Oct/2018

Issued To: General

Completed Status: 25 Oct 2018

Stock Ref: 1410000

Opera A/c: 00001365

Order Number: ORD94735

Notes:

24 Oct 2018 08:21:20 AM Catherine Spence
Shipping Wed 24 Oct 2018

Issues:130856

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001770 1430309 ORD94060

Issue ID #127932

Date Created 13/Sep/2018

Issued To: General

Completed Status: 18 Sep 2018

Stock Ref: 1430309

Opera A/c: 00001770

Order Number: ORD94060

Notes:

13 Sep 2018 10:02:53 AM Sarah Walton

See Attached Notes

SRS66695

Issues:127932

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002191 1480001 ORD93962

Issue ID #127514

Date Created 06/Sep/2018

Issued To: General

Completed Status: 07 Sep 2018

Stock Ref: 1480001

Opera A/c: 00002191

Order Number: ORD93962

Notes:

06 Sep 2018 11:25:18 AM Sarah Walton

See Attached Notes

SRS66702

07 Sep 2018 07:59:33 AM Catherine Spence

Shipping Fri 07 Sep 2018

Issues:127514

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002191 1480001 ORD96524

Issue ID #137733

Date Created 07/Feb/2019

Issued To: General

Completed Status: 08 Feb 2019

Stock Ref: 1480001

Opera A/c: 00002191

Order Number: ORD96524

Notes:

07 Feb 2019 08:26:53 AM Catherine Spence

Shipping Thu 07 Feb 2019

Issues:137733

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002380 1410000 ORD98673

Issue ID #147834

Date Created 20/Jun/2019

Issued To: General

Completed Status: 28 Jun 2019

Stock Ref: 1410000

Opera A/c: 00002380

Order Number: ORD98673

Notes:

20 Jun 2019 08:00:55 AM Catherine Spence
Back Order - Production

Issues:147834

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00002380 1410000 ORD98825

Issue ID #148561

Date Created 01/Jul/2019

Issued To: General

Completed Status: 09 Jul 2019

Stock Ref: 1410000

Opera A/c: 00002380

Order Number: ORD98825

Notes:

01 Jul 2019 08:25:56 AM Catherine Spence
In Production

03 Jul 2019 12:44:34 PM Sarah Walton
See Attached Notes
Followed this up with CG

03 Jul 2019 03:51:54 PM Catherine Spence
original order was picked and invoiced by mistake, as stock was for another customer, item was credited
and a replacement order was put onto the system. this is in production. Cg 03/07/19

09 Jul 2019 07:37:34 AM Catherine Spence
Shipping Tue 09 Jul 2019

Issues:148561

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003836 1430288 ORD94077

Issue ID #127949

Date Created 13/Sep/2018

Issued To: General

Completed Status: 14 Sep 2018

Stock Ref: 1430288

Opera A/c: 00003836

Order Number: ORD94077

Notes:

13 Sep 2018 02:09:37 PM Sarah Walton

See Attached Notes

SRS66679

Issues:127949

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003880 1410000 ORD99133

Issue ID #149986

Date Created 22/Jul/2019

Issued To: General

Completed Status: 24 Jul 2019

Stock Ref: 1410000

Opera A/c: 00003880

Order Number: ORD99133

Notes:

22 Jul 2019 07:57:23 AM Catherine Spence
Back Order - Production

Issues:149986

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00004127 1410000 ORD96521

Issue ID #137725

Date Created 07/Feb/2019

Issued To: General

Completed Status: 07 Feb 2019

Stock Ref: 1410000

Opera A/c: 00004127

Order Number: ORD96521

Notes:

07 Feb 2019 08:18:51 AM Catherine Spence

Shipping Thu 07 Feb 2019

Issues:137725

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00004670 1410000 ORD93031

Issue ID #123807

Date Created 11/Jul/2018

Issued To: General

Completed Status: 11 Jul 2018

Stock Ref: 1410000

Opera A/c: 00004670

Order Number: ORD93031

Notes:

11 Jul 2018 08:19:37 AM Catherine Spence

Shipping Wed 11 Jul 2018

Issues:123807

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00005210 1410000 ORD91139

Issue ID #116010

Date Created 12/Mar/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 1410000

Opera A/c: 00005210

Order Number: ORD91139

Notes:

12 Mar 2018 08:15:09 AM Catherine Spence

Shipping Mon 12 Mar 2018

Issues:116010

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006388 1410000 ORD91134

Issue ID #116005

Date Created 12/Mar/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 1410000

Opera A/c: 00006388

Order Number: ORD91134

Notes:

12 Mar 2018 08:14:33 AM Catherine Spence

Shipping Mon 12 Mar 2018

Issues:116005

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006454 1410000 ORD91239

Issue ID #116442

Date Created 19/Mar/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 1410000

Opera A/c: 00006454

Order Number: ORD91239

Notes:

19 Mar 2018 07:47:50 AM Catherine Spence
Back Order - Production

Issues:116442

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006454 1410000 ORD97821

Issue ID #143494

Date Created 26/Apr/2019

Issued To: General

Completed Status: 26 Apr 2019

Stock Ref: 1410000

Opera A/c: 00006454

Order Number: ORD97821

Notes:

26 Apr 2019 07:43:26 AM Catherine Spence
Shipping Fri 26 Apr 2019

Issues:143494

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006523 1410000 ORD94092

Issue ID #128193

Date Created 18/Sep/2018

Issued To: General

Completed Status: 24 Sep 2018

Stock Ref: 1410000

Opera A/c: 00006523

Order Number: ORD94092

Notes:

18 Sep 2018 08:40:18 AM Catherine Spence
Back Order - Production

Issues:128193

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006559 1410000 ORD97116

Issue ID #140309

Date Created 14/Mar/2019

Issued To: General

Completed Status: 15 Apr 2019

Stock Ref: 1410000

Opera A/c: 00006559

Order Number: ORD97116

Notes:

14 Mar 2019 08:20:17 AM Catherine Spence
Back Order - Production

Issues:140309

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006562 1410000 ORD98387

Issue ID #146448

Date Created 03/Jun/2019

Issued To: General

Completed Status: 01 Jul 2019

Stock Ref: 1410000

Opera A/c: 00006562

Order Number: ORD98387

Notes:

03 Jun 2019 08:09:58 AM Catherine Spence

Back Order - Supplier

28 Jun 2019 07:53:57 AM Catherine Spence

Shipping Fri 28 Jun 2019

Issues:146448

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006571 1410000 ORD98353

Issue ID #146445

Date Created 03/Jun/2019

Issued To: General

Completed Status: 11 Jun 2019

Stock Ref: 1410000

Opera A/c: 00006571

Order Number: ORD98353

Notes:

03 Jun 2019 08:09:11 AM Catherine Spence

Back Order - Production

11 Jun 2019 07:52:54 AM Catherine Spence

Shipping Tue 11 Jun 2019

Issues:146445

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006727 1410000 ORD91073

Issue ID #115746

Date Created 07/Mar/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 1410000

Opera A/c: 00006727

Order Number: ORD91073

Notes:

07 Mar 2018 08:11:44 AM Catherine Spence
Back Order - Production

Issues:115746

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007218 1410000 ORD95343

Issue ID #133061

Date Created 28/Nov/2018

Issued To: General

Completed Status: 29 Nov 2018

Stock Ref: 1410000

Opera A/c: 00007218

Order Number: ORD95343

Notes:

28 Nov 2018 08:45:31 AM Catherine Spence
Repair - Awaiting quote approval

Issues:133061

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007518 1430309 ORD95274

Issue ID #133281

Date Created 30/Nov/2018

Issued To: General

Completed Status: 27 Dec 2018

Stock Ref: 1430309

Opera A/c: 00007518

Order Number: ORD95274

Notes:

30 Nov 2018 12:43:14 PM Catherine Spence

Shipping Next Week

Ship with other orders

04 Dec 2018 07:38:35 AM Catherine Spence

See Attached Notes

Issues:133281

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007909 0013110 ORD96721

Issue ID #138568

Date Created 19/Feb/2019

Issued To: General

Completed Status: 19 Feb 2019

Stock Ref: 0013110

Opera A/c: 00007909

Order Number: ORD96721

Notes:

19 Feb 2019 07:47:26 AM Catherine Spence
Shipping Tue 19 Feb 2019

19 Feb 2019 07:47:27 AM Catherine Spence

Issues:138568

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007909 1410000 ORD94495

Issue ID #129985

Date Created 10/Oct/2018

Issued To: General

Completed Status: 16 Oct 2018

Stock Ref: 1410000

Opera A/c: 00007909

Order Number: ORD94495

Notes:

10 Oct 2018 08:29:47 AM Catherine Spence

In Production

Issues:129985

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00011608 1410000 ORD94086

Issue ID #128025

Date Created 14/Sep/2018

Issued To: General

Completed Status: 17 Sep 2018

Stock Ref: 1410000

Opera A/c: 00011608

Order Number: ORD94086

Notes:

14 Sep 2018 07:57:36 AM Catherine Spence
Shipping Fri 14 Sep 2018

Issues:128025

VIAMED Sales And Marketing - Post Market Surveillance

File 66 V1000 Foetal Heart Simulator Risk File Updated

Issue ID #149652

Date Created 16/Jul/2019

Issued To: Derek Lamb

Completed Status: 17 Jul 2019

Stock Ref: 0013110

Notes:

Risk file has changed, VM3COP27.12 Needs reviewing for 66 V1000 Foetal Heart Simulator as the Risk assessment has changed

Issues:149652

VIAMED Stock Meeting - Stock Queries

Need a stock check,

Issue ID #136252

Date Created 16/Jan/2019

Issued To: Robert Connor

Completed Status: 23 Jan 2019

Notes:

Added by Derek Lamb sent to Robert Connor
1430330 V1000 - Plastic Carrying Case

16 Jan 2019 Derek Lamb
1430331V1000 - Rear Label for Carrying Case
1450000Packing box - V1000

16 Jan 2019 Derek Lamb
Created Related Issue #136315
Added by Derek Lamb sent to Robert Connor
2520001 Microstim DB3 - Patient Lead.
2520003 Microstim DB3 - Patient Lead.

2530100 Microstim DB3 Tester PCB
2530104 Microstim DB3 Tester - Diode
2530105 Microstim DB3 Tester - LED

3210071 Single use silicone round facemask

16 Jan 2019 Derek Lamb
Created Related Issue #136316
Added by Derek Lamb sent to Robert Connor
4420505 IRMA CO2 analyzer

21 Jan 2019 Robert Connor
Opera adjustments
1430330: -106
1430331: +20
1450000: -13

23 Jan 2019 Derek Lamb

Issues:136252

General Maintenance Requirements - Computer Maintenance

New Email address: For servicing

Issue ID #124533

Date Created 23/Jul/2018

Issued To: Derek Lamb

Completed Status: 24 Jul 2018

Notes:

Added by Catrin Hird sent to Derek Lamb

Please can you set up the following address to be sent to the main inbox as well as mine.

Thanks

service@viamed.co.uk

1410000

24 Jul 2018 Derek Lamb

Done

24 Jul 2018 Catrin Hird

thanks

Issues:124533

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #143740

Date Created 01/May/2019

Issued To: Derek Lamb

Completed Status: 08 May 2019

Notes:

System Generated

Task To be Completed

List any production jobs started more 30 Days ago.

List any production jobs which QA date is more 30 Days ago.

03 May 2019 Derek Lamb

1410000Catherine Spence03/07/18Catherine Spence03/07/18 (304)Philip Crossley

just the test uhnits over 30 days

Issues:143740

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #139390

Date Created 01/Mar/2019

Issued To: Derek Lamb

Completed Status: 07 Mar 2019

Notes:

System Generated

Task To be Completed

List any production jobs started more 30 Days ago.

List any production jobs which QA date is more 30 Days ago.

04 Mar 2019 Derek Lamb
aside from the 1410000 all upto date

Issues:139390

VIAMED Stock Meeting - VIAMED Stock Meeting

Production In Production List (556)

Issue ID #137345

Date Created 01/Feb/2019

Issued To: Derek Lamb

Completed Status: 07 Feb 2019

Notes:

System Generated

Task To be Completed

List any production jobs started more 30 Days ago.

List any production jobs which QA date is more 30 Days ago.

04 Feb 2019 Derek Lamb

just the long standing 1410000 for test units

Issues:137345

VIAMED Management Meeting - Other

Repair codes V1000

Issue ID #127518

Date Created 06/Sep/2018

Issued To: Derek Lamb

Completed Status: 22 Nov 2018

Notes:

Added by Steve Nixon sent to Derek Lamb

On Repair Codes, where does the third column come from.

With 1440000 FOETAL is spelled as FEOTAL. Suggest chnaging this to just V1000

Can I edit & add to the codes?

Need to add:

1480001 Foetal Heart Simulator V1000 - Calibration Certificate

V1000

Calibration

06 Sep 2018 Derek Lamb

you need to check the opera description as that looks like it was the source of the orginial barcode label description,

thats still in the stock extra -old page, guess it should be moved to the new stock extra page
fixed the intrastats record,

1480001 description will come from the opera description first,

Issues:127518

VIAMED Stock Meeting - Sale or Returns
Request Scanning Item to Sale or return

Issue ID #134718

Date Created 20/Dec/2018

Issued To: Catherine Spence

Completed Status: 04 Jan 2019

Notes:

Added by Steve Hardaker sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference:

1410000 - V1000

Ref: Mark Francis.

28 Dec 2018 Catherine Spence

id: 1311239

Issues:134718

VIAMED Stock Meeting - Sale or Returns
Request Scanning Item to Sale or return
Issue ID #127347
Date Created 04/Sep/2018
Issued To: Catherine Spence
Completed Status: 05 Sep 2018

Notes:

Added by Kate Griffiths sent to Catherine Spence
Please scan to Sale or Returns Location ID34132 Stock Reference:1410000 x1. SOR 877

04 Sep 2018 Catherine Spence
1263854

05 Sep 2018 Kate Griffiths
done

Issues:127347

VIAMED Stock Meeting - Sale or Returns
Request Scanning Item to Sale or return

Issue ID #122612

Date Created 20/Jun/2018

Issued To: Catherine Spence

Completed Status: 04 Jul 2018

Notes:

Added by Steve Hardaker sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference:

1x 1410000 - V1000

Ref SOR857 - Wexham Park.

25 Jun 2018 Catherine Spence

1263853

04 Jul 2018 Steve Hardaker

Sent on SOR857.

Issues:122612

VIAMED Stock Meeting - Sale or Returns

Request Scanning Item to Sale or return - SOR896

Issue ID #137668

Date Created 06/Feb/2019

Issued To: Catherine Spence

Completed Status: 06 Feb 2019

Notes:

Added by Sophie Lines sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1410000 x1

06 Feb 2019 Catherine Spence
232584

06 Feb 2019 Sophie Lines
done

Issues:137668

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR857

Issue ID #126478

Date Created 21/Aug/2018

Issued To: Steve Hardaker

Completed Status: 01 Oct 2018

Notes:

Added by Catherine Spence sent to Steve Hardaker

SOR ID857

Originally added by :Steve Hardaker

Wexham Park Hospital

Adeel Mughal

Medical Electronics Department

Wexham

Slough

SL2 4HL

Returned : 1410000 PR02586A10

Sold on ord 93676

29 Aug 2018 Steve Hardaker

Invoiced 11/7/18 on IN157638 but the goods were sent in error, should have been Invoice Only. Credited and re-invoiced on IN158322. See also issue 126422.

01 Oct 2018 Catherine Spence

Issues:126478

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR877

Issue ID #128258

Date Created 18/Sep/2018

Issued To: Kate Griffiths

Completed Status: 01 Oct 2018

Notes:

Added by Catherine Spence sent to Kate Griffiths

SOR ID877

Originally added by :Kate Griffiths

Royal Blackburn Hospital

Matthew Crook

Medical Engineering

Haslingden Road

Blackburn

BB2 3HH

Returned : 1410000 PR02586A11

18 Sep 2018 Kate Griffiths

done

01 Oct 2018 Catherine Spence

Issues:128258

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR892

Issue ID #137744

Date Created 07/Feb/2019

Issued To: Steve Hardaker

Completed Status: 14 Feb 2019

Notes:

Added by Catherine Spence sent to Steve Hardaker

SOR ID892

Originally added by :Steve Hardaker

Derriford Hospital

Mark Francis

Clinical Engineering

Derriford Road

Plymouth

PL6 8DH

Returned : 1410000 PR02673A14

Sold on ORD96521

07 Feb 2019 Steve Hardaker

14 Feb 2019 Catherine Spence

Issues:137744

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR896

Issue ID #139326

Date Created 28/Feb/2019

Issued To: Ryan Swaine

Completed Status: 01 Mar 2019

Notes:

Added by Catherine Spence sent to Ryan Swaine

SOR ID896

Originally added by :Sophie Lines

METLOG Deutschland GmbH

Simon Grigull

Nordring 67

Niedernberg

Germany

D-63843

Returned : 1410000 PR0495A11

28 Feb 2019 Ryan Swaine

01 Mar 2019 Catherine Spence

Issues:139326

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR900

Issue ID #144824

Date Created 13/May/2019

Issued To: Steve Hardaker

Completed Status: 21 May 2019

Notes:

Added by Catherine Spence sent to Steve Hardaker

SOR ID900

Originally added by :Zoey Teal

Princess Alexandra Hospital

Louise Pengelly

EBME

Hamstel Road

Harlow
CM20 1QX

Returned : 1410000 PR0495A11

Sold on ord98059

13 May 2019 Steve Hardaker

21 May 2019 Catherine Spence

Issues:144824

VIAMED Stock Meeting - Sale or Returns

Sale Return SOR900 Princess Alexandra Hospital

Issue ID #140318

Date Created 14/Mar/2019

Issued To: Zoey Teal

Completed Status: 24 Apr 2019

Notes:

14 Mar 2019 Zoey Teal Issue Generated from SOR

14 Mar 2019 Zoey Teal

Next Action Changed From AUTO_SOR To Catherine Spence SOR900
1 x 1410000 for a trial

14 Mar 2019 Catherine Spence
trying to look for a demo unit for this

21 Mar 2019 Catherine Spence
id: 232584

02 Apr 2019 Catherine Spence

02 Apr 2019 Catherine Spence

Next Action Changed From Catherine Spence To Zoey Teal

03 Apr 2019 Zoey Teal
Completed

Issues:140318

VIAMED Sales And Marketing - VIAMED Sales And Marketing

Send Service Offers (607)

Issue ID #125772

Date Created 09/Aug/2018

Issued To: Derek Lamb

Completed Status: 14 Aug 2018

Notes:

System Generated

Task To be Completed

10 Aug 2018 Catrin Hird

Next Action Changed From Catrin Hird To Derek Lamb I think the system is bring up old listings, for example

993750

IN146298

1410000

25 Aug 2016

Does this mean that even though they are more than a year ago we should still do? Or are we just doing ones now from 2017?

10 Aug 2018 Derek Lamb
may as well do them :)

Issues:125772

Intrastats - Intrastats

Serviceable Items: Clear

Issue ID #124534

Date Created 23/Jul/2018

Issued To: Derek Lamb

Completed Status: 24 Jul 2018

Notes:

Added by Catrin Hird sent to Derek Lamb

Please can you clear the list of Servicable items. I have contacted all UK unique customers for:

0310002

0310097

0310030

0310031

0310032

0310034

1410000

From tomorrow we are then able to contact the customers which come up on the list.

Will these be by date or will they get notice of the service period running out?

24 Jul 2018 Derek Lamb

cleared the list,

currently its looking just at new sales a year ago, and or srs returns a year ago,

I can change it to 11 months i guess for early warning of a service due

24 Jul 2018 Catrin Hird

Perfect thanks

Issues:124534

Marketing Job Logger - Marketing Job Logger
Servicing Letters - V1000 and Tom Thumb
Issue ID #125306
Date Created 02/Aug/2018
Issued To: Steve Nixon
Completed Status: 06 Aug 2018

Notes:

Copy Issue Main Issue #125304

Added by Sarah Walton sent to Catrin Hird

We have had customers phoning up with regards to the V1000 servicing letter sent out recently. They have queried the price. The part number on the letter is for the certificate only (1480001), not the service and certificate (1480000) which is £45.00 plus £10.00 carriage.

See attached.

Derek, are we going to have to honour this until the next mailing goes out? If so, can you authorise to proceed at £35.00 plus £10.00 or advise otherwise.

06 Aug 2018 Sarah Walton

Issues:125306

Marketing Job Logger - Marketing Job Logger
Servicing Letters - V1000 and Tom Thumb
Issue ID #125305
Date Created 02/Aug/2018
Issued To: Derek Lamb
Completed Status: 06 Aug 2018

Notes:

Copy Issue Main Issue #125304

Added by Sarah Walton sent to Catrin Hird

We have had customers phoning up with regards to the V1000 servicing letter sent out recently. They have queried the price. The part number on the letter is for the certificate only (1480001), not the service and certificate (1480000) which is £45.00 plus £10.00 carriage.

See attached.

Derek, are we going to have to honour this until the next mailing goes out? If so, can you authorise to proceed at £35.00 plus £10.00 or advise otherwise.

03 Aug 2018 Derek Lamb

yes

06 Aug 2018 Sarah Walton

Issues:125305

Marketing Job Logger - Marketing Job Logger
Servicing Letters - V1000 and Tom Thumb

Issue ID #125304

Date Created 02/Aug/2018

Issued To: Steve Nixon

Completed Status: 06 Aug 2018

Linked Files

02 Aug 2018 V1000 Service Letter

Notes:

Added by Sarah Walton sent to Catrin Hird

We have had customers phoning up with regards to the V1000 servicing letter sent out recently. They have queried the price. The part number on the letter is for the certificate only (1480001), not the service and certificate (1480000) which is £45.00 plus £10.00 carriage.

See attached.

Derek, are we going to have to honour this until the next mailing goes out? If so, can you authorise to proceed at £35.00 plus £10.00 or advise otherwise.

03 Aug 2018 Catrin Hird

Urgent Flag Changed To On The letter is regarding the certificate of calibration not a service. Therefore it is the right part number and price.

The service is different, the letter is regarding the testing the V1000 and providing calibration certificate. A service is more indepth.

You need to speak with SN on his return for clarification, or speak with Phil for him to confirm what the difference is between the 2 if you are unsure.

03 Aug 2018 Catrin Hird

Urgent Flag Changed To Off I've emailed Steve for clarification

06 Aug 2018 Sarah Walton

Next Action Changed From Catrin Hird To Steve Nixon I spoke to Steve several weeks ago and we had a conversation about both these part numbers. He agreed that we should get rid of the calibration certificate part number and just use the service and certificate one, so I am a little confused!
I will speak to him when he gets back in the office.

06 Aug 2018 Sarah Walton

Issues:125304

Marketing Job Logger - Marketing Job Logger
Servicing Letters - V1000 and Tom Thumb
Issue ID #124541
Date Created 23/Jul/2018
Issued To: Sarah Walton
Completed Status: 23 Aug 2018

Notes:

Copy Issue Main Issue #124538
Added by Catrin Hird sent to Gail Bell
INFORMATION ONLY ISSUE DO NOT ADD NOTES!
Two mailings have been sent out this week regarding servicing offer.

Please find attached copies of letter.

Should you have any queries please let me know.

02 Aug 2018 Sarah Walton
Created Related Issue #125304
Added by Sarah Walton sent to Catrin Hird
We have had customers phoning up with regards to the V1000 servicing letter sent out recently. They have queried the price. The part number on the letter is for the certificate only (1480001), not the service and certificate (1480000) which is £45.00 plus £10.00 carriage.
See attached.
Derek, are we going to have to honour this until the next mailing goes out? If so, can you authorise to proceed at £35.00 plus £10.00 or advise otherwise.

Issues:124541

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129827

Date Created 08/Oct/2018

Issued To: Zoey Teal

Completed Status: 09 Oct 2018

Notes:

Copy Issue Main Issue #129822

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129827

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129826

Date Created 08/Oct/2018

Issued To: Sophie Lines

Completed Status: 08 Oct 2018

Notes:

Copy Issue Main Issue #129822

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129826

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129825

Date Created 08/Oct/2018

Issued To: Sarah Walton

Completed Status: 08 Oct 2018

Notes:

Copy Issue Main Issue #129822

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129825

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129824

Date Created 08/Oct/2018

Issued To: Kate Griffiths

Completed Status: 09 Oct 2018

Notes:

Copy Issue Main Issue #129822

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129824

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129823

Date Created 08/Oct/2018

Issued To: Gail Bell

Completed Status: 09 Oct 2018

Notes:

Copy Issue Main Issue #129822

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129823

VIAMED Sales And Marketing - Existing Good Products

V1000 Certificate of Calibration and Servicing

Issue ID #129822

Date Created 08/Oct/2018

Issued To: Emily Hanson

Completed Status: 08 Oct 2018

Notes:

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Please can everyone make themselves aware of the wording used regarding the V1000 Certificate of Calibration and Servicing. These can be found in the FAQs of 1410000.

Issues:129822

VIAMED Feedback - Product Feedback Negative

V1000 failures - needs a response

Issue ID #100588

Date Created 11/Aug/2017

Issued To: Steve Nixon

Completed Status: 24 Apr 2019

Notes:

Added by Steve Hardaker sent to Steve Nixon

Huntleigh are reporting more failures of the V1000 due to the membrane keypad, John Hughes stated in an email:

"I've got 3 units in need of repair, they've got the same fault where they won't switch on.

We've had this problem before and it's getting a bit tedious having to send the units back to get the membrane changed.

Is there anything that you can do to improve the membrane so it lasts?"

I have given him a returns number (SRS66150), they were sold March 5 but I assume we will do these under warranty as its a recurring issue with the membrane?

Please can you contact John Hughes to advise what steps we plan to take to rectify this moving forward?

11 Aug 2017 Steve Nixon

As discussed previously, I have asked the keypad membrane manufacturer to investigate this. I'm awaiting their report.

23 Sep 2017 Derek Lamb

Added for reference 1410000

29 Oct 2017 Steve Nixon

Urgent Flag Changed To Off As discussed the fault has been traced to keypad design issue. The keypad design has now been updated and will be used for future orders. In the meantime MG, PC & JC know how to rectify existing units using a bead of silicone to protect the exposed area of flex circuit. MG should be creating a procedure.

01 Nov 2017 Steve Hardaker Are we going to consider this as a design flaw and replace the keypad FOC for any units that are returned with this failure regardless of warranty status, or will we insist on it being chargeable?

22 Aug 2018 Derek Lamb

future orders have a modified track layout,
existing builds are rectified by a bead of silicone

Issues:100588

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123898

Date Created 12/Jul/2018

Issued To: Zoey Teal

Completed Status: 13 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123898

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123897

Date Created 12/Jul/2018

Issued To: Steve Hardaker

Completed Status: 12 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123897

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123896

Date Created 12/Jul/2018

Issued To: Sophie Lines

Completed Status: 13 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123896

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123895

Date Created 12/Jul/2018

Issued To: Sarah Walton

Completed Status: 23 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123895

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123894

Date Created 12/Jul/2018

Issued To: Ryan Swaine

Completed Status: 12 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123894

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123893

Date Created 12/Jul/2018

Issued To: Philip Crossley

Completed Status: 13 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123893

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123892

Date Created 12/Jul/2018

Issued To: Michael Green

Completed Status: 19 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123892

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123891

Date Created 12/Jul/2018

Issued To: Kate Griffiths

Completed Status: 20 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123891

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123890

Date Created 12/Jul/2018

Issued To: Gail Bell

Completed Status: 17 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123890

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123889

Date Created 12/Jul/2018

Issued To: Derek Lamb

Completed Status: 12 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123889

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123888

Date Created 12/Jul/2018

Issued To: Catherine Spence

Completed Status: 19 Jul 2018

Notes:

Copy Issue Main Issue #123887

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123888

VIAMED Sales And Marketing - Any other business

V1000 FAQ aditions

Issue ID #123887

Date Created 12/Jul/2018

Issued To: Catrin Hird

Completed Status: 13 Jul 2018

Notes:

Added by Steve Nixon sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

On the stock page (1410000) please review the two latest V1000 FAQs:

Why does the V1000 generate a waveform of double bursts

Why is there a 30 bpm setting

Issues:123887

VIAMED Stock Meeting - Any Other Business

V1000 keypad fault

Issue ID #96591

Date Created 13/Jun/2017

Issued To: Michael Green

Completed Status: 04 Jan 2019

Linked Files

13 Jun 2017 Modified V1000 pic 1

13 Jun 2017 Modified V1000 pic 2

13 Jun 2017 Modified V1000 pic 3, indicators

13 Jun 2017 Burnt out keypad track

21 Aug 2017 1430295 V1000 keypad test report

21 Aug 2017 Keypad 1

21 Aug 2017 Keypad 2

21 Aug 2017 Keypad 3

10 Oct 2017 Schurter production process `traveller` notes

22 Nov 2017 Design Changes QC28 B form to be filled in

23 Nov 2017 1430295 specification drawing C5288-25 Proof, Issue C (2017-10-10)

23 Nov 2017 QC 28 Design Changes.odt _ID23998 1430295 2017-11-22

23 Nov 2017 QC 28 Design Changes.odt _ID23998 1430295 2017-11-23

Notes:

Added by Steve Nixon sent to Philip Crossley

See attached images, is this a fault that we have seen before, with the track burnt out? If so, how many times? Do we have samples of damaged keypads? I will discuss with the keypad manufacturer; either design issue with our circuit or design/fault issue with the keypad membrane. We need to resolve this one.

In the returns reporting there are three keypad faults listed, are they effectively the same. If so, perhaps we should clean the codes to `Replaced faulty keypad membrane`.

Serviced with new Keypad; 10 faults

Replaced Keypad; 2 faults

membrane keys not working; 7 faults

Out of 406 units sold, 19 keypad faults (4.68%)

13 Jun 2017 Steve Nixon
email from customer:

Dear Zoey Teal,

Thank you for your kindly reply.

In our factory, we have three units of this model, but it is easy to broken.

Please check the attachment. is there any technological improvement now?

And how much for this model now?

Looking forward to your kindly reply.

Best regards

Mabel Wong
Sales Manager

Foshan Shunde Changxing Ultrasonic Instrument.Co.,Ltd.

13 Jun 2017 Steve Nixon
Hi Zoe

Apart from using a different transducer, the basic design hasn't changed.

Can they let us know the serial numbers of the units. We need to investigate how the keypad has been damaged.

The units look very dirty and there is evidence of a lot of fluid spillage.

Looks like they have modified the unit instead of replacing the keypad.

Do they want us to check and service their units?

Steve

14 Jun 2017 Steve Nixon
Tomorrow we will send 10 examples to the manufacturer for investigation, see email below:

Hi Steve,

Thanks for the information.

The returns number controlling this issue is RMA DUK002820, once we receive the product we will produce an 8D report with preventative measures, corrective actions and a root cause.

The returns address is:

SCHURTER Electronics Ltd.
29 Pembroke Road,
Aylesbury,
Bucks.
HP20 1DB.

Regards,

Arron Russell
Head of Management Systems
SCHURTER Electronics Limited
Tel +44 (0)1296 319030
Fax +44 (0)1296 319012
arron.russell@schurter.co.uk
www.schurter.com

21 Aug 2017 Steve Nixon
Followed up with the manufacturer, see attached report from Schurter:

21 Aug 2017 Steve Nixon
email from Schurter:

Hi Steve,

Good to talk to you earlier,

As discussed I have attached a copy of the Test certificate for the test I have run against a stock part which we have. This ran powered for one million actuations to which no damage nor failure was found, I have since restarted the test for a further one million actuations at a higher power to which I also expect to find no failure.

There seems to be some moisture potentially being trapped within the part as the small area of exposed

silver along the base of the tail has signs of corrosion on the powered track which eventually causes the parts to fail. A couple of proposed solves to this would be to cover the small area of exposed silver by either bringing the dielectric down the tail to cover where the silver is exposed or to bring the adhesive further up the part to protect the open area of silver.

I shall in the mean time investigate to why this area is exposed and also put into place a solve to this issue after speaking with some of my colleagues.

I shall keep you informed as to any decisions and potential changes we could make.

Regards,

Darren Rhodes
Quality Supervisor
SCHURTER Electronics Limited
Tel +44 (0)1296 319023
Fax +44 (0)1296 319012
darren.rhodes@schurter.co.uk
www.schurter.com

21 Aug 2017 Steve Nixon

I have asked Schurter to look into redesign.

They said that they did not design the layout, but they Danielson/Schurter will have designed the mechanical construction plates, so they should take responsibility for the small gap that is leaving the tracks exposed to moisture.

In the meantime will discuss with PC, MG, JC. We can apply a small bead of silicone to the exposed areas of the tracks. The problem looks to be that moisture is attacking the exposed track, I believe that this is exacerbated by there being no adhesive along the lower edge of the membrane. This is probably where moisture (ultrasound gel/cleaning fluid) is getting in.

The keypad design has passed functional tests and the tracks are adequate for the power consumption.

21 Aug 2017 Steve Nixon

See attached images:
Keypad 1, 2 & 3

Keypad 1: Burnt out track (track 3 from LHS) can be clearly seen where junction of the green coloured flex tail meets the main assembly. This is a common fault location.

Keypad 2: Shows that there is no adhesive on the lower edge cut out section, therefore tracks underneath are not effectively sealed against moisture.

Keypad 3: Shows the small gap (approx. 1mm) along the edge of the green flex tail, where the track is not protected against potential damage from flexing and/or moisture corrosion.

22 Aug 2017 Philip Crossley

I happen to have 3 relatively new V1000s in from Huntleigh Healthcare all needing keypads. PR01883A16, A13 and A17 on SRN28750, 51 and 52.

I will try the silicone bead on all 3 and put a black X in the bottom corner for easy identification later.

08 Sep 2017 Steve Nixon

Next Action Changed From Philip Crossley To Derek Lamb On Tuesday also reviewed with MG and JC in lieu of PC absence.

MG will silicone production units and repairs. He will also produce procedures for both.

Still waiting to hear back from Schurter.

20 Sep 2017 Steve Nixon

Tried to follow up with Darren Rhodes at Schurter, left voicemail.

21 Sep 2017 Derek Lamb
Created Related Issue #103452
Added by Derek Lamb sent to Derek Lamb
V1000 keypad fault
1410000 Foetal Heart Simulator model V1000.

10 Oct 2017 Steve Nixon
Discussed with Darren Rhodes at Schurter.

He will send up drawing of the redesign and said he would also supply a copy of their production process 'traveller' notes.

10 Oct 2017 Steve Nixon
See attached:
Schurter production process 'traveller' notes.

23 Nov 2017 Steve Nixon See attached the revised design for the V1000 keypad 1430295
C5288-25 Proof, Issue C (2017-10-10).

To be implemented when we next place the next process a P.O.

23 Nov 2017 Steve Nixon
See attached completed QC28 B forms:

QC 28 Design Changes.odt _ID23998 1430295 2017-11-22 Application of silicone bead to service and production units

QC 28 Design Changes.odt _ID23998 1430295 2017-11-23 Implementaion of keypad revised design change

23 Nov 2017 Steve Nixon

Next Action Changed From Derek Lamb To Michael Green Michael, can you please upload copies of your procedures, so that we have them on the same issue. Once you have done this we can close the issue.

Issues:96591

VIAMED Sales And Marketing - Mailshots UK

V1000 Servicing Options Letter V2

Issue ID #128263

Date Created 18/Sep/2018

Issued To: Steve Nixon

Completed Status: 30 Oct 2018

Linked Files

18 Sep 2018 V1000 Servicing Letter v2 2018-09-18

24 Oct 2018 V1000 Servicing Letter v2 2018-09-24

Notes:

Added by Catrin Hird sent to Steve Nixon

1410000

Please find attached updated V1000 servicing options letter as per our meeting.

Hard copy and proof sheet also provided.

This will be used for the rolling servicing list Gail is contacting 11 months before servicing is due.

24 Oct 2018 Catrin Hird

Updated as per notes on original.

Amended copy provided to SN with original proof sheet.

Digital copy attached to issue.

24 Oct 2018 Catrin Hird

Signed off by SN

30 Oct 2018 Catrin Hird

Issues:128263

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1227

Issue ID #126418

Date Created 20/Aug/2018

Issued To: Kate Griffiths

Completed Status: 20 Aug 2018

Notes:

Web Site Question ID 1227

17/08/18

xingmedical@gmail.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

CAMILO A CONTRERAS A

XINGMEDICAL

xingmedical@gmail.com

Colombia

Type: Pricing

Part number

1410000

Request further Information on

20 Aug 2018 Kate Griffiths

Referred to Biosancta, and emailed Biosancta as per RS. KG 20.8.18

20 Aug 2018 Kate Griffiths

Referred to Biosancta, and emailed Biosancta as per RS. KG 20.8.18

Issues:126418

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1278

Issue ID #132918

Date Created 26/Nov/2018

Issued To: Kate Griffiths

Completed Status: 26 Nov 2018

Notes:

Web Site Question ID 1278

24/11/18

juaco587@gmail.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

Joaquin Bedoya

Hospital San Juan de Dios de Honda

IngenierÃ-a biomedica

juaco587@gmail.com

Colombia

Type: General

Regards

I need the price of the foetal heart monitor, and the portfolio with others related equipments

Request further Information on

26 Nov 2018 Kate Griffiths asked Biosancta if I can refer Joaquin to them, if so, email Joaquin. KG 26.11.18

Issues:132918

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1279

Issue ID #132921

Date Created 26/Nov/2018

Issued To: Kate Griffiths

Completed Status: 26 Nov 2018

Notes:

Web Site Question ID 1279

26/11/18

kane.mcglashan@waikatodhb.health.nz

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

kane

Waikato

Biomedical Engineering

kane.mcglashan@waikatodhb.health.nz

New Zealand

Type: General

Hi

Do you have a distributor for your products in New Zealand, I am looking for a V1000 Foetal simulator?

Request further Information on

26 Nov 2018 Kate Griffiths

replied asking if they would like to purchase from us or Intermed, NZ KG 26.11.18

26 Nov 2018 Kate Griffiths

replied asking if they would like to purchase from us or Intermed, NZ KG 26.11.18

Issues:132921

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1302

Issue ID #136865

Date Created 24/Jan/2019

Issued To: Kate Griffiths

Completed Status: 24 Jan 2019

Notes:

Web Site Question ID 1302

24/01/19

louise.pengelly@pah.nhs.uk

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

Louise

Princess Alexandra Hospital

EBME

louise.pengelly@pah.nhs.uk

United Kingdom EU

Type: Pricing

Please may I have a price quote for the following Fetal heart simulator 1410000

Request further Information on

24 Jan 2019 Kate Griffiths

replied with price and leaflet. KG 24.1.19

Issues:136865

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1312

Issue ID #139538

Date Created 04/Mar/2019

Issued To: Kate Griffiths

Completed Status: 05 Mar 2019

Notes:

Web Site Question ID 1312

28/02/19

gabriel.searles@ge.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

Gabriel Searles

GE Healthcare

Maternal Infant Care

gabriel.searles@ge.com

United States

Type: General

Looking for quote for the fetal heart simulator. Please quote 2, 3, or 4. Also what would the lead time be?

Part number

1410000

Product name

V1000 Foetal Heart Simulator

GTIN / EAN13

5051826001936

Request further Information on

05 Mar 2019 Kate Griffithsdone. replied with US dist. prices. KG 5.3.19

Issues:139538

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 1317

Issue ID #140079

Date Created 11/Mar/2019

Issued To: Sophie Lines

Completed Status: 11 Mar 2019

Notes:

Web Site Question ID 1317

11/03/19

teknisidayaprima@gmail.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

Tion Wahyu

Daya Prima Mandiri Jaya, PT

Technision

teknisidayaprima@gmail.com

Indonesia

Type: Technical

hello, my name is, I am from Indonesia, I have a fetal viamed v1000 simulator, but the device is broken, do you have spare parts with part number P / N 1430301 and how much is it?

thanks

Request further Information on

11 Mar 2019 Sophie Lines

done

11 Mar 2019 Sophie Lines

Issues:140079

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 7790

Issue ID #147315

Date Created 14/Jun/2019

Issued To: Kate Griffiths

Completed Status: 14 Jun 2019

Notes:

Web Site Question ID 7790

14/06/19

jaspal.saimbi@wsht.nhs.uk

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

jaspal saimbi

worthing hospital

medical electronics

jaspal.saimbi@wsht.nhs.uk

United Kingdom EU

Type: General

hi

we have a v1000 which is
overdue its service date

Request further Information on

14 Jun 2019 Kate Griffiths

replied asking for serial no. KG 14.6.19

Issues:147315

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 7791

Issue ID #147424

Date Created 17/Jun/2019

Issued To: Kate Griffiths

Completed Status: 17 Jun 2019

Notes:

Web Site Question ID 7791

15/06/19

jartermega@gmail.com

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

1410000 V1000 Foetal Heart Simulator

Jaime Arturo

JarterMEGA

MetrologÃ-a

jartermega@gmail.com

Colombia

Type: Pricing

En Colombia tienen distribuciÃ³n

Request further Information on

17 Jun 2019 Kate Griffiths
ref to Biosancta as per RS. KG 17.6.19

Issues:147424

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 :

Tester unit not for use on patients

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 :

Tester unit not for use on patients