

V1000 Foetal Heart Simulator

Class I

Carried out by Derek Lamb 14 / 11 / 22



- 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 number upto date

Supplier Review

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

Comments on Suppliers:

supplier reviews upto date for suppliers we still use

Sales Information

Stock Reference	Description	2016	2017	2018	2019	2020	2021	2022
0013110	Carrying case.							
1410000	Foetal Heart Simulator model V1000.							
1420000	Wall mount for Foetal He							
1420001	Case protector for Foeta							
1430270	PCB - Foetal Heart Simul							
1430284	V1000 Case with keypad							
1430285	V1000 Case.							
1430286	V1000 Case Seal Kit.							
1430287	V1000 Battery Compartmen							1
1430288	V1000 Battery Clip 4 x A							1
1430295	V1000 Keypad Membrane							1
1430296	V1000 label set (2) - ca							
1430297	V1000 intensity control							
1430300	V1000 PCB Assembly.							
1430301	V1000 Transducer Mount.							
1430302	V1000 Transducer.							
1430303	V1000 Transducer mountin							
1430304	V1000 Transducer mountin							
1430305	V1000 Transducer mountin							
1430306	V1000 Transducer screw.							
1430307	V1000 Transducer washer.							
1430308	V1000 Transducer nut.							
1430309	V1000 Transducer interface cushion.							3
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							3
1480001	Foetal Heart Simulator V1000 -							1
1490000	Leaflet - V1000 Foetal h							
1490001	Instructions for Use - V							
1490002	V1000 Product Application Sheet							

Comments on Sales Information:

limited sales of parts

Countries Review

Country	2016	2017	2018	2019	2020	2021	2022
CO Colombia							[X]
Romania							[X]
Scotland							[X]
United Kingdom							[X]

Comments on Sales to Countries:

no issues with countries

Comments on Risks with Sales to Countries:

no risk

Returns and Q.A. Fails Review

Stock Reference	Fault	2016	2017	2018	2019	2020	2021	2022
0013110	No Fault Found							
0013110	No Fault Return To Stock							
1410000	Battery Contacts Replaced And Calibrated	1		1				
1410000	Broken Wire			1				
1410000	Calibration Checked		6	9	21	6	17	24
1410000	Clean And Check	1						
1410000	Dead							
1410000	Faulty Board							
1410000	Membrane Keys Not Working							
1410000	New			1				1
1410000	No Fault Found		1		3			
1410000	Replaced Interface Cushion		1					
1410000	Replaced Keyboard Interface Cushion		2					
1410000	Replaced Keypad	2	4					
1410000	Replaced Keypad And Checked Calibration		5	4	2	2		1
1410000	Replaced PCB And Calibrate	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	12	4					
1410000	Rewired and checked calibration						1	1
1410000	Serviced And Calibrated	20	9		1			
1410000	Serviced And Calibration Checked		11	33	21	34	31	39
1410000	Serviced with new battery case and contacts							1
1410000	Serviced with new battery contacts and calibration checked.						1	3
1410000	Serviced With New Keypad	6	5		2	1	1	1
1410000	Serviced with new lower case and calibration checked.							4
1410000	Serviced With New Pot And Keypad							
1410000	Transducer Cushion Interface Replaced.							
1410000	Unchecked - Returned To Stock							
1410000	Unit Leaking							
1420001	No Fault Found							
1420001	No Fault Return To Stock		1					
1420001	Unchecked - Returned To Stock							

Comments on Returns:

a few replacements on battery contacts, mainly calibration services.

Comments on Risks with Returns and Potential Re-work:

no risk with returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

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 instructions

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F7/F8 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:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
86602	Viamed V1000 Foetal Heart Simulator Warranty Statement	05/04/22
81494	V1000 Foetal Heart Simulator Risk analysis reports	02/02/22
72831	V1000 Foetal Heart Simulator Clinical Trials Reports Reviews and	21/10/21

Comments on Document Changes:

file maintenance updates only, no other changes

Comments on Risks with Document Changes:

Internal Issues Review Number of Issues reviewed: 19

Issue ID	Subject
	·
271831	1410000 Foetal Heart Simulator V1000 Memo
237140	Backorder I0007915 1410000 132994
277770	File 66 V1000 Foetal Heart Simulator Risk File Updated
249983	File 66 V1000 Foetal Heart Simulator Risk File Updated
276758	Product Failures New Codes Review (750)
249486	Product Failures New Codes Review (750)
244927	Product Failures New Codes Review (750)
239590	Product Failures New Codes Review (750)
268143	PVM1830 1430300 12/08/2022
83776	Returned Items SOR745
249956	Reund due to no stock of 1410000 - CVM134057
110807	Sending Service Offers
250558	Web Site Question ID 8632
251074	Web Site Question ID 8637
251620	Web Site Question ID 8642
259745	Web Site Question ID 8694
265058	Web Site Question ID 8712
267091	Web Site Question ID 8721
275778	Web Site Question ID 8747

Comments on Issues:

no problems or risks found in the issue system

Comments on Risks with Issues:

VIAMED Stock Meeting - Stock Queries

1410000 Foetal Heart Simulator V1000 Memo

Issue ID #271831

Date Created 13/Sep/2022 Issued To: Steve Nixon

Completed Status: 12 Oct 2022

Notes:

Added by Catrin Hird sent to Steve Nixon

Please can you update memo further to discussions in meeting on Wednesday 7th and any updates you received on Friday 9th thanks.

12 Oct 2022 Steve Nixon Updated.

12 Oct 2022 Catrin Hird

Thank you

- Sales Back Orders Review - By Customer **Backorder I0007915 1410000 132994**

Issue ID #237140

13306 10 #237 140

Date Created 01/Jan/1970

Issued To:

Completed Status: 23 Mar 2022

Stock Ref: 1410000 Order Number: 132994

Notes:

23 Mar 2022 Catherine Spence waiting on parts to be able to make items

23 Mar 2022 Catherine Spence SN has sourced some parts

VIAMED Sales And Marketing - Post Market Surveilance

File 66 V1000 Foetal Heart Simulator Risk File Updated

Issue ID #277770

Date Created 14/Nov/2022 Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0013110

Notes:

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

077770

VIAMED Sales And Marketing - Post Market Surveilance

File 66 V1000 Foetal Heart Simulator Risk File Updated

Issue ID #249983

Date Created 02/Feb/2022 Issued To: Derek Lamb

Completed Status: 07 Feb 2022

Stock Ref: 0013110

Notes:

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

02 Feb 2022 Derek Lamb speaker failed, risk done, no capa required

Product Failures New Codes Review (750)

Issue ID #276758

Date Created 04/Nov/2022 Issued To: Derek Lamb

Completed Status: 10 Nov 2022

Notes:

System Generated Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

04 Nov 2022 Derek Lamb
0111263 requires Cleaning!
PCB Fault - no cap required
1410000 requires Cleaning!
serviced, no cap required

Product Failures New Codes Review (750)

Issue ID #249486

Date Created 28/Jan/2022 Issued To: Derek Lamb

Completed Status: 03 Feb 2022

Notes:

System Generated Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

28 Jan 2022 Derek Lamb

0110182 requires Cleaning! liner 02 fault no capa 0110439 requires Cleaning! liner 02 fault no capa 1410000 requires Cleaning! Service no capa

28 Jan 2022 Derek Lamb

28 Jan 2022 Derek Lamb Done

Product Failures New Codes Review (750)

Issue ID #244927

Date Created 10/Dec/2021 Issued To: Derek Lamb

Completed Status: 16 Dec 2021

Notes:

System Generated Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

10 Dec 2021 Derek Lamb
1410000 requires Cleaning!
Speaker wiring fault,
first instance of anything like this,
no capa required at this time

Product Failures New Codes Review (750)

Issue ID #239590

Date Created 22/Oct/2021 Issued To: Derek Lamb

Completed Status: 29 Oct 2021

Notes:

System Generated
Task To be Completed

Review Intrastats Page:

Returns-> Repair codes Clean up

If New Faults have entered the system,

Review the Stock Repairs and apply a clean code and tag Fault / user or No Fault.

Complete all Stock References until the list is empty

22 Oct 2021 Derek Lamb

0110039 requires Cleaning!

Manufacturing Error - return to supplier

1410000 requires Cleaning!
service no capa required

7910211 requires Cleaning!
Vandagraph erratic reading no capa reqied at this point
8010007 requires Cleaning!
No test equipment return to supplier
8010022 requires Cleaning!
erratic temp compenastion return to supplier no capa required

- Back Order Report

PVM1830 1430300 12/08/2022

Issue ID #268143

Date Created 04/Aug/2022 Issued To: Robert Connor

Completed Status: 04 Aug 2022

Notes:

PVM1830 1430300 Estimated ship to us date changed to 12 / 08 / 2022

VIAMED Stock Meeting - Sale or Returns

Returned Items SOR745

Issue ID #83776

Date Created 17/Nov/2016 Issued To: Katie Evans

Completed Status: 14 Nov 2022

Notes:

Added by Jonathan Connor sent to Katie Evans SOR ID745 Originally added by :Katie Evans Royal Blackburn Hospital Tahani Suliman

E.B.M.E. (Electronics Dept.) Haslingden Road Blackburn Lancashire BB2 3HH

Returned: 1410000 PR02194A10

18 Nov 2016 Katie Evans Completed

-____

24 Nov 2016 Jonathan Connor Thanks

VIAMED General Issue - General Accounts Issues

Reund due to no stock of 1410000 - CVM134057

Issue ID #249956

Date Created 02/Feb/2022 Issued To: Helen Lamb

Completed Status: 02 Feb 2022

Linked Files

02 Feb 2022 CareNX INnovations Pvt Ltd

Notes:

Added by Kate Griffiths sent to Helen Lamb

CareNX have asked to be refunded for 1 x 1410000 as we are currently unable to produce them. The amount is \$1063.40. Their bank details are as follows:

Account Name: CareNX INnovations Pvt Ltd Bank Account - HDFC Bank Branch- Charchgate, Mumbai Account no- 50200038029407 IFSC code- HDFC0000501

02 Feb 2022 Helen Lemb

02 Feb 2022 Helen Lamb refund done please find the bank notification attached. Which you can send them if you want.

02 Feb 2022 Kate Griffiths Thank you, will do

Office Meeting - Office Procedures

Sending Service Offers

Issue ID #110807

Date Created 21/Dec/2017 Issued To: Derek Lamb

Completed Status: 14 Nov 2022

Linked Files

21 Dec 2017 V1000 Email Template 21 Dec 2017 V1000 Letter Template

Notes:

Added by Katie Evans sent to Katie Evans Derek.

A brief overview of what I have been doing. From lookup tab>Worklists?Chase Possible Service Items.

Clicking on 1410000 as TT letter not yet signed off, see issue 89789.

Click on get info, click on barcode, if the invoice number starts with CRE or it has an (r) then I haven't been sending as they are credits or returns (to my understanding) sent the letter as standard through GoldMine with template.

The GBP end user letter template is in Q>goldmine>Template>Katie>V1000 Service AMENDED.dot For GBP distributors I have simply amended the price.

The tricky part is separating the end users from the distributors.

For EUR/USD service offers, I made a very similar email template but used a table (particularly useful for distributors who may have bought loads) please find attached

To help me with the distributor purchases, you built me a table on this page:

https://www.vmsecure.me.uk/intranet/operainfo/showstockaccount.php?zz=1&vui=57&user=Katie%20Evans &idp=raztfgzrBcdOg&submenu=&sessionid=717df487131d62116fdcdb61812981af&catagory=141%20%20F oetal%20Heart%20-

%20Prod&stk=1410000&account=I0007909&name=METLOG%20Deutschland%20GmbH

I hope this is useful. When I went through this with Emily, the parts she found to be too difficult were figuring out who is a distributor and figuring out which were credits or returns.

21 Dec 2017 Katie Evans

Next Action Changed From Katie Evans To Derek Lamb

27 Dec 2017 Katie Evans

Issues:110807

Web Site Question ID 8632

Issue ID #250558

Date Created 08/Feb/2022

Issued To: Zoey Teal

Completed Status: 08 Feb 2022

Notes:

Web Site Question ID 8632 08/02/22 cristiana.neto@iberdata.pt Information Request to Viamed Limited at the https://www.viamed.co.uk/uk/ WebSite

1410000 V1000 Foetal Heart Simulator Cristiana Madeira Iberdata

cristiana.neto@iberdata.pt Portugal EU (excluding Azores and Maderia) Type: Technical

Hello,

Does this equipment need calibration? I cant find anything in the manual.

Request further Information on

08 Feb 2022 Zoey Teal Emailed and dealt with. Completed

08 Feb 2022 Zoey Teal

Completed

Web Site Question ID 8637

Issue ID #251074

Date Created 14/Feb/2022 Issued To: Sophie Lines

Completed Status: 14 Feb 2022

Notes:

Web Site Question ID 8637
14/02/22
remssolutions@gmail.com
Information Request to Viamed Limited at the https://www.viamed.co.uk/uk/ WebSite

1410000 V1000 Foetal Heart Simulator Sean Fortune REMS Solutions Biomedical services remssolutions@gmail.com Trinidad and Tobago

Type: Pricing

what is your pricing on the V1000 Foetal Heart Simulator. Where can i get one for my company

Request further Information on

14 Feb 2022 Sophie Lines Done

14 Feb 2022 Sophie Lines

Web Site Question ID 8642

Issue ID #251620

Date Created 18/Feb/2022 Issued To: Sophie Lines

Completed Status: 21 Feb 2022

Notes:

Web Site Question ID 8642

17/02/22

itthichote@measuretronix.com

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

1410000 V1000 Foetal Heart Simulator

Itthichote

Measuretronix Ltd.

Sales Engineer

itthichote@measuretronix.com

Thailand

Type: Pricing

Dear Sales,

We are Measuretronix Ltd. who is medical equipment analyzer distributor from Thailand.

Please send quotation â€~V1000 Foetal Heart Simulator' with certificate for the best price to us as soon as possible. (For warranty 2 year)

https://www.viamed.co.uk/uk/?uid= and sessionid= and g= and mobile= and and page=productview and cat=370 and subcat=415 and productid=1410000

Looking forward to hearing from you.

Best Regards. Itthichote Sales Engineer Measuretronix Ltd.

Request further Information on	
18 Feb 2022 Sarah Walton	

Next Action Changed From Sarah Walton To Sophie Lines Are you ok to deal with this? Thanks

21 Feb 2022 Sophie Lines Done

21 Feb 2022 Sarah Walton

Web Site Question ID 8694

Issue ID #259745

Date Created 10/May/2022 Issued To: Kate Griffiths

Completed Status: 10 May 2022

Notes:

Web Site Question ID 8694

10/05/22

medrep@mweb.co.za

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

1410000 V1000 Foetal Heart Simulator

Anton Nell

Medical Repair Services

medrep@mweb.co.za

South Africa Type: General

Price on viamed v100 fetal heart simulator

Request further Information on

40 May 2000 Kata Oriffith a

10 May 2022 Kate Griffiths replied with end user pricing and long lead time as per RS

Web Site Question ID 8712

Issue ID #265058

Date Created 01/Jul/2022 Issued To: Kate Griffiths

Completed Status: 01 Jul 2022

Notes:

Web Site Question ID 8712

01/07/22

yosbanis.diat@dhsd.limpopo.gov.za

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

1410000 V1000 Foetal Heart Simulator

Yosbanis

Limpopo department of health

Clinical engineering

yosbanis.diat@dhsd.limpopo.gov.za

South Africa Type: Pricing

I could like to know the price of this simulator and if you have any seller in South Africa

Request further Information on

01 Jul 2022 Kate Griffiths ref to Arrabon as per RS

Web Site Question ID 8721

Issue ID #267091

Date Created 25/Jul/2022 Issued To: Kate Griffiths

Completed Status: 25 Jul 2022

Notes:

Web Site Question ID 8721 25/07/22 ross.barnes@tgh.nhs.uk Information Request to Viamed Limited at the https://www.viamed.co.uk/uk/ WebSite

1410000 V1000 Foetal Heart Simulator Ross Tameside Hospital Medical Equipment Services ross.barnes@tgh.nhs.uk United Kingdom EU Type: Pricing

Hi There, i would like to get a quote for a V1000 Foetal Heart Simulator

Kind Regards Ross Barnes

Request further Information on

25 Jul 2022 Kate Griffiths replied with price etc

Web Site Question ID 8747

Issue ID #275778

Date Created 26/Oct/2022 Issued To: Kate Griffiths

Completed Status: 27 Oct 2022

Notes:

Web Site Question ID 8747
26/10/22
rofaif@nextleveltechnologies.org
Information Request to Viamed Limited at the https://www.viamed.co.uk/uk/ WebSite

rofaif saleh next level technologies sdn bhd biomedical rofaif@nextleveltechnologies.org Malaysia Type: Pricing

Request for quotation for Part number 1410000

Product name : V1000 Foetal Heart Simulator

GTIN / EAN13 5051826001936

Request further Information on

27 Oct 2022 Kate Griffiths
gave end user pricing as per RS and mentioned unavailable at this time

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 :

not medical device, simulator

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:

not medical device, simulator