



VIA MED

Bluepoint Temperature Probes

Reusable and Disposable Temperature Probe

Class IIa

NBOG MD0101

Carried out by Derek Lamb
27 / 10 / 17



VIA MED

-  Stock References Review
-  Supplier Review
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Stock References Review

Stock Reference	Description
0212009	Temperature probe - Oesophageal/Rectal.
0212010	Temperature probe - Oesophageal/Rectal.
0212011	Temperature probe - Oesophageal/Rectal.
0212012	Temperature probe - Oesophageal/Rectal.
0212013	Temperature probe - Oesophageal/Rectal.
0212014	Temperature probe - Oesophageal/Rectal.
0212015	Temperature probe - Oesophageal/Rectal.
0212016	Temperature probe - Oesophageal/Rectal.
0212017	Temperature probe - Oesophageal/Rectal.
0212018	Temperature probe - Oesophageal/Rectal.
0212019	Temperature probe - Oesophageal/Rectal.
0212020	Temperature probe - Oesophageal/Rectal.
0212021	Temperature probe - Skin contact.
0212022	Temperature probe - Skin contact.
0212023	Temperature probe - Skin contact.
0212024	Temperature probe - Skin contact.
0212025	Temperature probe - Skin contact.
0212026	Temperature probe - Skin contact.
0212027	Temperature probe - Skin contact.
0212028	Temperature probe - Skin contact.
0212029	Temperature probe - Skin contact.
0212030	Temperature probe - Skin contact.
0212031	Temperature probe - Skin contact.
0212032	Temperature probe - Skin contact.

Comments on Stock references review:

Stock reference upto date for now,
unsure if references will changed when we finally get Bluepoints name on the labels

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0212009	Temperature probe - Oeso	00009300	TRRE 01-00-2009	Bluepoint Medical	A
0212010	Temperature probe - Oeso	00009300	TRRE 01-00-2010	Bluepoint Medical	A
0212011	Temperature probe - Oeso	00009300	TRRE 01-00-2011	Bluepoint Medical	A
0212012	Temperature probe - Oeso	00009300	TRRE 01-00-2012	Bluepoint Medical	A
0212013	Temperature probe - Oeso	00009300	TRRE 01-00-2013	Bluepoint Medical	A
0212014	Temperature probe - Oeso	00009300	TRRE 01-00-2014	Bluepoint Medical	A
0212015	Temperature probe - Oeso	00009300	TRRE 01-00-2015	Bluepoint Medical	A
0212016	Temperature probe - Oeso	00009300	TRRE 01-00-2016	Bluepoint Medical	A
0212017	Temperature probe - Oeso	00009300	TRRE 01-00-2017	Bluepoint Medical	A
0212018	Temperature probe - Oeso	00009300	TRRE 01-00-2018	Bluepoint Medical	A
0212019	Temperature probe - Oeso	00009300	TRRE 01-00-2019	Bluepoint Medical	A
0212020	Temperature probe - Oeso	00009300	TRRE 01-00-2020	Bluepoint Medical	A
0212021	Temperature probe - Skin	00009300	TRRE 01-00-2021	Bluepoint Medical	A
0212022	Temperature probe - Skin	00009300	TRSC 01-00-2022	Bluepoint Medical	A
0212023	Temperature probe - Skin	00009300	TRSC 01-00-2023	Bluepoint Medical	A
0212024	Temperature probe - Skin	00009300	TRRE 01-00-2024	Bluepoint Medical	A
0212025	Temperature probe - Skin	00009300	TRRE 01-00-2025	Bluepoint Medical	A
0212026	Temperature probe - Skin	00009300	TRRE 01-00-2026	Bluepoint Medical	A
0212027	Temperature probe - Skin	00009300	TRRE 01-00-2027	Bluepoint Medical	A
0212028	Temperature probe - Skin	00009300	TRRE 01-00-2028	Bluepoint Medical	A
0212029	Temperature probe - Skin	00009300	TRRE 01-00-2029	Bluepoint Medical	A
0212030	Temperature probe - Skin	00009300	TRSC 01-00-2030	Bluepoint Medical	A
0212031	Temperature probe - Skin	00009300	TRSC 01-00-2031	Bluepoint Medical	A
0212032	Temperature probe - Skin	00009300	TRSC 01-00-2032	Bluepoint Medical	A

Comments on Suppliers:

Suppliers up to date

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0212009	Temperature probe - Oeso	1		2			6	
0212010	Temperature probe - Oeso	5		2			7	
0212011	Temperature probe - Oeso	3		2	9		12	61
0212012	Temperature probe - Oeso							
0212013	Temperature probe - Oeso							
0212014	Temperature probe - Oeso	15						
0212015	Temperature probe - Oeso							
0212016	Temperature probe - Oeso							
0212017	Temperature probe - Oeso							
0212018	Temperature probe - Oeso				3			
0212019	Temperature probe - Oeso							
0212020	Temperature probe - Oeso	7	5	5	1	2	-1	2
0212021	Temperature probe - Skin		3			10		
0212022	Temperature probe - Skin					5		
0212023	Temperature probe - Skin				5	1	1	
0212024	Temperature probe - Skin							
0212025	Temperature probe - Skin							
0212026	Temperature probe - Skin						3	1
0212027	Temperature probe - Skin							
0212028	Temperature probe - Skin							
0212029	Temperature probe - Skin							
0212030	Temperature probe - Skin				17	10	15	2
0212031	Temperature probe - Skin	1				8		
0212032	Temperature probe - Skin			4	2	12	5	7

Comments on Sales Information:

limited sales.

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
AU Austria							
CH Chile	[X]						
ES Estonia					[X]	[X]	[X]
GR Greece				[X]			
HU Hungary						[X]	
IN India							
IS Israel	[X]	[X]	[X]				
MA Malaysia							
OM Oman			[X]				
P Poland	[X]		[X]	[X]	[X]	[X]	
PO Portugal							
RO Romania						[X]	[X]
SA South Africa						[X]	[X]
T Turkey							
UK United Kingdom	[X]	[X]		[X]	[X]	[X]	[X]

Comments on Sales to Countries:

selling to multiple countries

Comments on Risks with Sales to Countries:

no risks with countries

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0212010	No Fault Return To Stock							
0212020	Cable Open Circuit							
0212021	No Fault Return To Stock					5		
0212030	Cable Split						3	
0212030	Open Circuit						10	
0212032	Physically Broken						2	

Comments on Returns:

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No changes,
but in process of moving to bluepoint labelled as the manufacturer.

Comments on Risks with Design Changes:

no notifications required

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
2952	400-AC Temperture Probes User Instructions	17/01/08

Comments on User Instructions:

Comments on Risks User Instructions:

no risk with ifu

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
17058	Temperature Probes BPM Labels 0212032	20/06/16
15360	Temperature Probes BPM Labels 0212031	05/08/15
15358	Temperature Probes BPM Labels 0212030	05/08/15
15356	Temperature Probes BPM Labels 0212029	05/08/15
15353	Temperature Probes BPM Labels 0212028	05/08/15
15351	Temperature Probes BPM Labels 0212027	05/08/15
15349	Temperature Probes BPM Labels 0212026	05/08/15
15347	Temperature Probes BPM Labels 0212025	05/08/15
15345	Temperature Probes BPM Labels 0212024	05/08/15
15343	Temperature Probes BPM Labels 0212023	05/08/15
15341	Temperature Probes BPM Labels 0212022	05/08/15
15339	Temperature Probes BPM Labels 0212021	05/08/15
15337	Temperature Probes BPM Labels 0212020	05/08/15
15335	Temperature Probes BPM Labels 0212019	05/08/15
15333	Temperature Probes BPM Labels 0212018	05/08/15
15331	Temperature Probes BPM Labels 0212017	05/08/15
15329	Temperature Probes BPM Labels 0212016	05/08/15
15327	Temperature Probes BPM Labels 0212015	05/08/15
15325	Temperature Probes BPM Labels 0212014	05/08/15
15323	Temperature Probes BPM Labels 0212013	05/08/15
15321	Temperature Probes BPM Labels 0212012	05/08/15
15319	Temperature Probes BPM Labels 0212011	05/08/15
15317	Temperature Probes BPM Labels 0212010	05/08/15
15315	Label 0212009	05/08/15
9169	No accessory labels	18/10/11
7092	Temperature Probes BPM Labels Tacking labels	20/05/10
6806	Temperature Probes BPM Labels 400AC	18/02/10
6805	Temperature Probes BPM Labels 400ACplug label II	18/02/10
6804	Temperature Probes BPM Labels 400AC plug label	18/02/10
6803	Temperature Probes BPM Labels 400AC Bag label	18/02/10
6802	Temperature Probes BPM Labels 400AC box label	18/02/10

Comments on Labels:

added a missing label from the files

Comments on Risks Labels:

no risks with labeling

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
18306	OBL Bluepoint Medical Contract OEM QA contract	21/12/16
18070	Bluepoint Temperature Probes Classification rationale..	15/11/16
18068	Bluepoint Temperature Probes medicinal substance human blood de...	15/11/16
18066	Bluepoint Temperature Probes Details of Clinical investigations	15/11/16
18064	Bluepoint Temperature Probes Evidence of Usability Human factors...	15/11/16
18062	Bluepoint Temperature Probes Software verification and validatio...	15/11/16
18060	Bluepoint Temperature Probes Detailed test results Device verif...	15/11/16
18058	Bluepoint Temperature Probes Risk management document for the sy...	15/11/16
18056	Bluepoint Temperature Probes Manufacturing process flow chart	15/11/16
18054	Bluepoint Temperature Probes Design input specification .	15/11/16
18052	Bluepoint Temperature Probes Solutions adopted to fulfil the Ess...	15/11/16
17858	Bluepoint Capnograph Location of responsibilities. documentatio...	09/11/16
17840	Sensatronics EC Declaration of Conformance	03/11/16
17838	Bluepoint Capnograph Location of responsibilities.	03/11/16
17632	Bluepoint Temperature Probes Description of intended use	28/09/16
17628	Bluepoint Capnograph Quality Assurance and Agreements Appendix ...	28/09/16
17626	Bluepoint Details of significant subcontractors	28/09/16
17625	Bluepoint Location of responsibilities.	28/09/16
17428	Viamed CE Certificate CE01389	07/09/16
17058	Temperature Probes BPM Labels 0212032	20/06/16
16797	Temperature Probes BPM Clinical Trials Reports Reviews and Post ...	20/04/16

Comments on Document Changes:

added extra documentation from bluepoint,
but we changing to be manufacturer officially by bluepoint using their CE

Comments on Risks with Document Changes:

no risks with files

Internal Issues Review

Number of Issues reviewed: 23

Issue ID	Subject
90671	Office Meeting Sales Back Orders Review - By Customer Backorder 00000620 0212030 ORD85263
73208	Office Meeting Sales Back Orders Review - By Customer Backorder 00006676 0212009 ORD80893
74072	Office Meeting Sales Back Orders Review - By Customer Backorder 00007539 0212032 ORD81052
74073	Office Meeting Sales Back Orders Review - By Customer Backorder 00007539 0212032 ORD81053
80200	Office Meeting Sales Back Orders Review - By Customer Backorder 00007545 0212026 ORD82481
106133	Office Meeting Sales Back Orders Review - By Customer Backorder 00011657 0212011 ORD88911
72999	Office Meeting Document Control Amendments needed Document Update Request (15362)
71883	Office Meeting Back Order Report POR10758 0212032 //
72014	Office Meeting Back Order Report POR10758 0212032 04/07/2016
71943	Office Meeting Back Order Report POR10758 0212032 10/06/2016
83259	Office Meeting Back Order Report POR11027 0212030 //
83250	Office Meeting Back Order Report POR11027 0212030 //
82807	Office Meeting Back Order Report POR11027 0212030 //
83370	Office Meeting Back Order Report POR11027 0212030 01/12/2016
84895	Office Meeting Purchase Back Orders Review POR11027 0212030 Have Been Delivered or Cancelled in Opera
82554	Office Meeting Repairs Review - General Progress of SRS65637
82553	Office Meeting Repairs Review - General Progress of SRS65637
80547	Office Meeting Any other business Reusable temperature probes
80514	Office Meeting Any other business Reusable temperature probes
104882	Office Meeting Sales Viamed Medical UK Sales lead - Temperature probes, Loughborough University
97154	Office Meeting Sales Temperature probe for SpaceLabs SL 2700 Ultraview
97153	Office Meeting Sales Temperature probe for SpaceLabs SL 2700 Ultraview
80450	Office Meeting Product Feedback Negative Temperature probes lifespan

Comments on Issues:

80450 VIAMED Feedback Product Feedback Negative Product Feedback Negative
Life sensors questioned,
have pushed the issue 80450 to see if its been resolved.

otherwise no issues for concern in the issue system

Comments on Risks with Issues:

no risks .

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000620 0212030 ORD85263

Issue ID #90671

Date Created 08/Mar/2017

Issued To: General

Completed Status: 08 Mar 2017

Stock Ref: 0212030

Opera A/c: 00000620

Order Number: ORD85263

Notes:

08 Mar 2017 07:47:06 AM Catherine Spence
Shipping Wed 08 Mar 2017

Issues:90671

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006676 0212009 ORD80893

Issue ID #73208

Date Created 20/Jun/2016

Issued To: General

Completed Status: 20 Jun 2016

Stock Ref: 0212009

Opera A/c: 00006676

Order Number: ORD80893

Notes:

20 Jun 2016 Catherine Spence
Shipping Mon 20 Jun 2016

Issues:73208

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007539 0212032 ORD81052

Issue ID #74072

Date Created 30/Jun/2016

Issued To: Jonathan Connor

Completed Status: 26 May 2017

Stock Ref: 0212032

Opera A/c: 00007539

Order Number: ORD81052

Notes:

30 Jun 2016 Catherine Spence
See Attached Notes
ship with next order

25 May 2017 04:17:08 PM Steve Nixon
00007539 Meditsiini Grupp

ORD81052 28/06/2016

ORD81053 28/06/2016

Why cant the temperature probe repairs be shipped?

25 May 2017 Ryan Swaine

Next Action Changed From Ryan Swaine To Jonathan Connor These should be posted by airmail ASAP.
JC, please can you take care of this?

26 May 2017 Jonathan Connor
Shipped

Issues:74072

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007539 0212032 ORD81053

Issue ID #74073

Date Created 30/Jun/2016

Issued To: General

Completed Status: 26 May 2017

Stock Ref: 0212032

Opera A/c: 00007539

Order Number: ORD81053

Notes:

30 Jun 2016 Catherine Spence
See Attached Notes
ship with next order

Issues:74073

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007545 0212026 ORD82481

Issue ID #80200

Date Created 28/Sep/2016

Issued To: General

Completed Status: 14 Nov 2016

Stock Ref: 0212026

Opera A/c: 00007545

Order Number: ORD82481

Notes:

28 Sep 2016 Katie Evans

See Attached Notes

Emailed to advise that their account is on stop

17 Oct 2016 03:33:53 PM Derek Lamb

test

28 Oct 2016 08:29:47 AM Katie Evans

No longer on stop

Issues:80200

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00011657 0212011 ORD88911

Issue ID #106133

Date Created 20/Oct/2017

Issued To: General

Completed Status: 20 Oct 2017

Stock Ref: 0212011

Opera A/c: 00011657

Order Number: ORD88911

Notes:

20 Oct 2017 07:41:05 AM Catherine Spence
Shipping Fri 20 Oct 2017

Issues:106133

BS EN ISO 13485:2003 - Document Control Amendments needed

Document Update Request (15362)

Issue ID #72999

Date Created 15/Jun/2016

Issued To: Derek Lamb

Completed Status: 27 Jun 2016

Linked Files

15 Jun 2016 0212032 Labels

Notes:

Added by Catrin Hird sent to Derek Lamb

Controlled Document (15362) Temperature Probes BPM Labels 0212032 Requires Updating

Updated address details and logo. Please upload

20 Jun 2016 Derek Lamb
done

27 Jun 2016 Catrin Hird
Thanks

Issues:72999

- Back Order Report

POR10758 0212032 //

Issue ID #71883

Date Created 23/May/2016

Issued To: Jonathan Connor

Completed Status: 23 May 2016

Notes:

POR10758 0212032 Estimated ship to us date changed to / /

Issues:71883

- Back Order Report

POR10758 0212032 04/07/2016

Issue ID #72014

Date Created 25/May/2016

Issued To: Jonathan Connor

Completed Status: 25 May 2016

Notes:

POR10758 0212032 Estimated ship to us date changed to 04 / 07 / 2016

Issues:72014

- Back Order Report

POR10758 0212032 10/06/2016

Issue ID #71943

Date Created 24/May/2016

Issued To: Jonathan Connor

Completed Status: 24 May 2016

Notes:

POR10758 0212032 Estimated ship to us date changed to 10 / 06 / 2016

Issues:71943

- Back Order Report

POR11027 0212030 //

Issue ID #83259

Date Created 10/Nov/2016

Issued To: Jonathan Connor

Completed Status: 10 Nov 2016

Notes:

POR11027 0212030 Estimated ship to us date changed to / /

Issues:83259

- Back Order Report

POR11027 0212030 //

Issue ID #83250

Date Created 10/Nov/2016

Issued To: Jonathan Connor

Completed Status: 10 Nov 2016

Notes:

POR11027 0212030 Estimated ship to us date changed to / /

Issues:83250

- Back Order Report

POR11027 0212030 //

Issue ID #82807

Date Created 03/Nov/2016

Issued To: Jonathan Connor

Completed Status: 03 Nov 2016

Notes:

POR11027 0212030 Estimated ship to us date changed to / /

Issues:82807

- Back Order Report

POR11027 0212030 01/12/2016

Issue ID #83370

Date Created 11/Nov/2016

Issued To: Jonathan Connor

Completed Status: 11 Nov 2016

Notes:

POR11027 0212030 Estimated ship to us date changed to 01 / 12 / 2016

Issues:83370

Purchase Back Orders Review - Purchase Back Orders Review

POR11027 0212030 Have Been Delivered or Cancelled in Opera

Issue ID #84895

Date Created 06/Dec/2016

Issued To: Michael Green

Completed Status: 06 Dec 2016

Notes:

Have Been Delivered or Cancelled in Opera

Issues:84895

VIAMED Stock Meeting - Repairs Review - General

Progress of SRS65637

Issue ID #82554

Date Created 31/Oct/2016

Issued To: Michael Green

Completed Status: 31 Oct 2016

Notes:

Copy Issue Main Issue #82553

Added by Steve Hardaker sent to Jonathan Connor

Service Repair Sheet:65637 SRN27688 Accessory 0212030 V150110404 Temp probe Skin contact..

These arrived on the 12th Oct but it doesnt look like the warranty ones have been replaced as yet.

Customer chasing as short on probes.

Please can you advise the status? Thanks.

31 Oct 2016 Steve Hardaker

Issues:82554

VIAMED Stock Meeting - Repairs Review - General

Progress of SRS65637

Issue ID #82553

Date Created 31/Oct/2016

Issued To: Jonathan Connor

Completed Status: 31 Oct 2016

Notes:

Added by Steve Hardaker sent to Jonathan Connor

Service Repair Sheet:65637 SRN27688 Accessory 0212030 V150110404 Temp probe Skin contact..

These arrived on the 12th Oct but it doesnt look like the warranty ones have been replaced as yet.

Customer chasing as short on probes.

Please can you advise the status? Thanks.

31 Oct 2016 Steve Hardaker

Urgent Flag Changed To Off Closing JCs copy of this so as not to add duplicate issues on same subject.

See issue 80450.

Issues:82553

VIAMED Sales And Marketing - Any other business

Reusable temperature probes

Issue ID #80547

Date Created 03/Oct/2016

Issued To: Catrin Hird

Completed Status: 14 Oct 2016

Notes:

Added by Steve Nixon sent to Catrin Hird

Catrin can you also update the leaflet as necessary. Sorry, I've referenced to 4000 Series above, should be 400-AC Series.

03 Oct 2016 Catrin Hird

Added to office job #699

03 Oct 2016 Catrin Hird

I've just looked up the Drager Temperature Probes connector and it states 7-pin, the Siemens connector is only 2 pin.

Are they only 2 pins connected??

03 Oct 2016 Steve Nixon

2 pins on the probe, but believe 7 on the monitor, so 5 blanks on the probe. If I'm wrong then so is Envitec, Integral Process, Exacon...

Please double check you connector images on the web site.

03 Oct 2016 Steve Nixon

You've left off paediatric on the introduction.

<http://www.viamed.co.uk/uk/?uid=&sessionid=&g=&i=2&page=catagory&cat=368&subcat=412>

04 Oct 2016 Catrin Hird

Sorry, the last comment, I didn't do that page. I'll have a look at it - Sorry don't know what you mean by missed off paediatric? 0212010,3,6,9,22,25,28,31 are all showing? Whats missing?

I've look up the Drager temperature probe and yes I can see what you mean. It does have the Siemens connector but states that the monitor is 7 pin. Thanks for the clarification. The connector images on the website show the front on of the connector so you can see the position of the pins.

04 Oct 2016 Steve Nixon

As long as our pics are clear on the web site?

They may have used a common to them 7 pin connector. Or it could be dedicated to temperature, but they have scope to add a dual channel, or other temperatures say for thermodilution...

05 Oct 2016 Catrin Hird

Ok noted thanks, added to office job 699

14 Oct 2016 Steve Nixon

Issues:80547

VIAMED Sales And Marketing - Any other business

Reusable temperature probes

Issue ID #80514

Date Created 03/Oct/2016

Issued To: Derek Lamb

Completed Status: 14 Oct 2016

Linked Files

03 Oct 2016 Temperature probe cross reference data 2016-10-03

Notes:

Added by Steve Nixon sent to Derek Lamb

Can we develop the web site further in terms of temperature probes. I have started working on a cross reference, note there won't always just be one result. Usually one result if compatibility with another probe, but when selecting a patient monitor you will get various results (up to 8), depending upon patient type (N,I,P,A) and sensor type (skin, rectal/oesophageal).

Derek, I have already added some data to the cross referenc. Can you activate it for the office and add it on-line please. I have also attached further data on a spreadsheet (220 records), can you please also add this to the cross reference. I will add more spreadsheet data in due course, initially mainly to cover Philips Medical.

Catrin:

<http://www.viamed.co.uk/uk/?uid=&sessionid=&g=&i=2&page=catagory&cat=368&subcat=412>

error 2012014 should be 0212014

You can label all the Siemens sensors as Dräger & Siemens

NOTE: Dräger can be spelt as Draeger. Americans spell it as Drager.

You can label all the HP sensors as Philips Healthcare & Hewlett Packard

On the web site is the Siemens connector flattened at one edge or completely circular? If circular, why show index groove at 11 O'clock?

Can you please develop some training materials.

Derek/Catrin Should we just rely on the cross reference, or should we also add a brief text main cross ref to each version's more information sheet? If so, I can supply the text.

Our sensors are compatible to the original YSI 400 series, which is the main standard for medical temperature sensors. Although, I have found that some modern day monitors still also use 700 and 900 series compatible sensors.

Brief history.

400 Series developed by YSI (yellow Springs Instruments).

YSI acquired by Measurement Specialities Inc.

Measurement Specialities Inc. acquired by TE Connectivity (formerly Tyco Electronics Ltd.)

For the 4000 series there are a few layers of competitors:

1) Low cost reusable, usually from Far East. If needed we could source these.

2) Mid-high range reusable . This is where our sensors sit. We are competing with the OEMs and also directly with the likes of Bluepoint, Envitec, Sensatronic, Medacx... We should be cheaper than the OEMs and our sensors are also autoclavable.

3) Disposables – If we believe we can access the market, then we can develop a range fairly easily.

NOTE: Exacon Scientific A/S (Denmark) were also a competitor. They appear to have ceased trading altogether. Due to this, I believe that Envitec and Bluepoint have had increased enquiries/sales.

NOTE: there are errors on competitors' cross-references.

NOTE: On an on-going basis I may still need to edit some of our cross-references after obtaining detailed information on monitor features and applications, e.g. not all may monitor neonates.

NOTE: Our 4000 Series sensors are autoclavable, so can replace competitors' autoclavable sensors and can of course be used to replace competitors' standard reusable sensors.

03 Oct 2016 Steve Nixon

Created Related Issue #80547

Added by Steve Nixon sent to Catrin Hird

Catrin can you also update the leaflet as necessary. Sorry, I've referenced to 4000 Series above, should be 400-AC Series.

03 Oct 2016 Steve Nixon

Didn't expect you to add straight away. I missed off `probe` from 4 entries so I have updated the X Ref. You probably already know, but if you select a monitor it just brings up one probe instead of a choice of up to 8.

03 Oct 2016 Steve Nixon

Can you add temperature probes to the pull down list on intrastats Xref.

<https://www.vmsecure.me.uk/intranet/databases/tedcomp/xrefsearch.php>

04 Oct 2016 Derek Lamb

oops i thought i had...
done

Issues:80514

VIAMED Sales And Marketing - Sales Viamed Medical UK
Sales lead - Temperature probes, Loughborough University
Issue ID #104882
Date Created 09/Oct/2017
Issued To: Steve Hardaker
Completed Status: 21 Oct 2017

Notes:

Added by Steve Nixon sent to Steve Hardaker
Sales lead via Bluepoint Medical

Josh Foster
Research Associate in Environmental Physiology
Environmental Ergonomics Research Centre
Loughborough University, LE11 3TU

Office: +44(0)1509 228315
Mobile: +44(0)7590 808009

Hello,

Please can I have a quote for the following items:

10 10 13 2017
10 10 13 2020
10 10 13 2011

Thanks,
Josh

Hello Josh,

the price depends from the quantity.

Kind regards
Dana

Ok – can I have a price for 10, 20, and 30 please.

Thanks
Josh

09 Oct 2017 Steve Hardaker
Sent pricing and leaflet, offered 10% discount off 10+ quantities on a per line basis.

18 Oct 2017 Steve Hardaker
Josh is placing an order for 1 x 0212009 neonatal oesophageal sensor for testing purposes and will purchase more if it works with their data logger.

Issues:104882

VIAMED Sales And Marketing - Sales

Temperature probe for SpaceLabs SL 2700 Ultraview

Issue ID #97154

Date Created 21/Jun/2017

Issued To: Ryan Swaine

Completed Status: 25 Jul 2017

Notes:

Copy Issue Main Issue #97153

Added by Steve Nixon sent to Katie Evans

The probes plug into a pig-tail adapter cable (700-00-31-00) that allows two probes to be connected.

SpaceLabs have 3 type of reusable temperature probes:

360175-001 YSI 400 Series, Oesophageal/rectal

118-0256-00 YSI 700 Series, Oesophageal/rectal

690-0028-00 YSI 700 Series, Skin

They don't have a 400 Series Skin probe. All their probes have right angled connectors.

SpaceLabs tech support assure me that the modules will accept both 400 Series and 700 Series probes, so our range of 400 Series probes should be OK.

0212012 Neonatal R/O

0212013 Paediatric R/O

0212014 Adult R/O

0212024 Neonatal skin

0212025 Paediatric skin

0212026 Adult skin

26 Jun 2017 Ryan Swaine

Issues:97154

VIAMED Sales And Marketing - Sales

Temperature probe for SpaceLabs SL 2700 Ultraview

Issue ID #97153

Date Created 21/Jun/2017

Issued To: Katie Evans

Completed Status: 25 Jul 2017

Notes:

Added by Steve Nixon sent to Katie Evans

The probes plug into a pig-tail adapter cable (700-00-31-00) that allows two probes to be connected.

SpaceLabs have 3 type of reusable temperature probes:

360175-001 YSI 400 Series, Oesophageal/rectal

118-0256-00 YSI 700 Series, Oesophageal/rectal

690-0028-00 YSI 700 Series, Skin

They don't have a 400 Series Skin probe. All their probes have right angled connectors.

SpaceLabs tech support assure me that the modules will accept both 400 Series and 700 Series probes, so our range of 400 Series probes should be OK.

0212012 Neonatal R/O

0212013 Paediatric R/O

0212014 Adult R/O

0212024 Neonatal skin

0212025 Paediatric skin

0212026 Adult skin

04 Jul 2017 Katie Evans

Thank you very much

Issues:97153

VIAMED Feedback - Product Feedback Negative

Temperature probes lifespan

Issue ID #80450

Date Created 03/Oct/2016

Issued To: Steve Nixon

Completed Status: Still Outstanding

Linked Files

14 Nov 2016 Temperature probe report SRS65637

Notes:

Added by Steve Hardaker sent to Steve Nixon

Paul Pichur at Bradford Royal advised that they do not feel that the Viamed temperature probes last anywhere near as long as original Philips originals.

After a lot of failures in what the end user thought was too short a period, they bought 5 original Philips ones to test this and said that have lasted longer than the Viamed sensors they replaced.

Returned 8 on SRS65637 (some under warranty, some not), I have added notes to the SRS to ask that the person testing them advises the causes of failure even for the out of warranty ones as it may help to improve the product.

03 Oct 2016 Steve Nixon

I assume we are talking about 0212030s? If so, only 40 ever sold, no returns.

Steve, we need to have a good look at these when they come in.

06 Oct 2016 Steve Hardaker

Next Action Changed From Steve Nixon To Jonathan Connor Customer has been disposing of them when they fail, they may have actually been outlasting their warranties but their experience is that they are not as good as the originals.

Jonathan, please can you let me know on this issue which types, quantities, date sold and warranty status? These may warrant deeper investigation. Thanks. See SRS65637

11 Oct 2016 Steve Hardaker

Update from the customer after I asked for further info on how long they have been lasting:

"Weve had a steady number reported to us since weve used them in our Neonatal unit. We did have a spare stock of them so its hard to judge how long since we have purchased them to how long they have been in service. I have thrown a few away in the past.

A senior member of staff asked me to keep an eye on the failure rate as she thought they were failing quite a lot, thats why we got some genuine Philips ones (which none have failed) a few months ago."

31 Oct 2016 Steve Hardaker

Urgent Flag Changed To On These arrived on the 12th Oct but it doesnt look like the warranty ones have been replaced as yet. Customer chasing as short on probes. Please can you advise the status? Thanks.

31 Oct 2016 Steve Hardaker

As you were not in, I spoke to Michael and he will take a look at them asap. Advised him we need to replace any failed warranty ones.

01 Nov 2016 Jonathan Connor

Np, he was looking to make a test unit end of last week but he was off friday. He is working on them at the moment

08 Nov 2016 Steve Hardaker
Created Related Issue #83057

Added by Steve Hardaker sent to Michael Green

Michael, please can you summarise the temperature probe repairs on SRS65637 into a Word doc and attach to this issue as we need to undertake a quality investigation and Steve N may need to send this report to Bluepoint.

Please can you put in as much detail as possible, not just the cause of failure. For example, if you are able to determine where the cables are broken, please add it. Where the cables are split or damaged. Whether there are signs of other damage, ie tears, nicks, damage possibly from cleaning fluids etc.

In short, the question we are trying to answer is "Why are these not lasting as long as the original Philips sensors?" Thanks.

14 Nov 2016 Steve Hardaker

Next Action Changed From Jonathan Connor To Steve NixonSteve, please see attached report from Michael. The majority are suffering from cable breaks, can the cable and overall build quality be improved?

27 Oct 2017 Derek Lamb

did anything happen with this?

stands out as its negative feedback and no final conclusion

Issues:80450

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 :

nothing found

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 :