



VIA MED

T Adaptors

Class IIa
Via Rule Rule 9
Assesment Route Annex II
NBOG MD 0101

Carried out by Derek Lamb
14 / 11 / 22



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
0120090	Oxygen sensor O ring.
0120098	Oxygen sensor flow diverter O ring 15mm
0120099	Oxygen Sensor Flow Diverter 15mm
0120100	`T` adapter. 22mm I.D. - 22mm O.D.
0120103	`T` adapter: 15mm paediatric circuits
0120106	`T` adapter. 22mm I.D. - 22mm O.D.
0120108	`T` adapter. 22mm O.D. - 22mm O.D.
0120109	`T` adapter non rebreathing.
0120110	Perfusion Circuit `T` Adapter.
0120121	FlowCheck
0120125	Connector: 22mm I.D. - 22mm I.D.
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm
0120128	Connector - 15mm I.D. - 22mm I.D.
0120129	Connector - 22mm O.D - 30mm O.D.
0120130	Connector 15mm O.D. - tapered barbed
0120131	Connector 15mm I.D./22mm O.D. - tapered
0120133	Connector 22mm I.D./30mm O.D. - tapered
0120139	Adapter 15mm I.D. - 10mm I.D
0120140	Adapter 15mm I.D. - 15mm I.D
0120141	Adapter 15mm I.D./22mm O.D. -
0120142	Adapter 15mm I.D./22mm O.D. -
0120149	Adapter 15mm I.D. - 10mm I.D
0120150	Adapter 15mm I.D. - 15mm I.D
0120151	Adapter 15mm I.D./22mm O.D. -
0120152	Adapter 15mm I.D. - 15mm I.D
0120153	Adapter 15mm I.D./22mm O.D. -
0120159	Adapter 15mm I.D. - 10mm I.D
0120160	FiO2 sensor adapter.
0120161	FiO2 activator for small bore tubing.
0120162	FiO2 activator for 15mm O2 sensors
0120163	FiO2 activator for 18mm O2 sensors
0120164	Spring loaded FiO2 sensor adapter.
0120165	Replacement `T` assembly for MT 100.
0120166	Replacement activator for MT 100.
0120200	Adult MDI Adapter.
0120201	Adult MDI Adapter.
0120202	Adult MDI Adapter.
0120203	Adult MDI Adapter.
0120204	Paediatric MDI Adapter.
0120205	Paediatric MDI Adapter.
0120206	MDI Adapter - Replacement Rubber Cap.

Stock Reference	Description
0120207	MDI Adapter.
0120208	MDI Adapter.
0120300	Wye Connector
0120301	Wye Connector with pressure port.
0120302	Wye Connector with temperature probe
0120303	Wye Connector with temperature probe
0120304	Temperature probe port cap.
0120305	Wye connector 60 degrees.
0120306	Wye connector 90 degrees.
0120307	Wye connector 60 degrees.
0120310	Auto PEEP measurement device.
0120400	`T` adapter. 22mm I.D. - 22mm O.D.
0120401	`T` adapter. 22mm I.D. - 22mm O.D.
0120402	`T` adapter. 22mm I.D. - 22mm O.D.

Comments on Stock references review:

stock references upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0120099	Oxygen Sensor Flow Diver				Needs Grading
0120103	`T` adapter: 15mm paedia				Needs Grading
0120130	Connector 15mm O.D. - t				Needs Grading
0120131	Connector 15mm I.D./22m				Needs Grading
0120133	Connector 22mm I.D./30m				Needs Grading
0120402	`T` adapter. 22mm I.D. -				Needs Grading
0120099	Oxygen Sensor Flow Diver	00009190		Vandagraph	B
0120121	FlowCheck	00011712	R217P18	Maxtec Inc.	A
0120100	`T` adapter. 22mm I.D. -	00011844	BE 125-1TD	Instrumentation Industri	B
0120106	`T` adapter. 22mm I.D. -	00011844	BE 117-W PK 10	Instrumentation Industri	B
0120108	`T` adapter. 22mm O.D. -	00011844	BE 125-1	Instrumentation Industri	B
0120109	`T` adapter non rebreat	00011844	BE 117 PK10	Instrumentation Industri	B
0120130	Connector 15mm O.D. - t	00011844		Instrumentation Industri	B
0120131	Connector 15mm I.D./22m	00011844		Instrumentation Industri	B
0120133	Connector 22mm I.D./30m	00011844		Instrumentation Industri	B
0120139	Adapter 15mm I.D. - 10m	00011844	PF 1510 PACK 50	Instrumentation Industri	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	B
0120141	Adapter 15mm I.D./22mm	00011844	KC 2124	Instrumentation Industri	B
0120152	Adapter 15mm I.D. - 15m	00011844	PF 1515 PACK 50	Instrumentation Industri	B
0120153	Adapter 15mm I.D./22mm	00011844	KC 2124 PK 100	Instrumentation Industri	B
0120159	Adapter 15mm I.D. - 10m	00011844	PF 1510 PACK 50	Instrumentation Industri	B
0120161	FiO2 activator for small	00011844	BE 101-3A	Instrumentation Industri	B
0120162	FiO2 activator for 15mm	00011844	ACT 15/22	Instrumentation Industri	B
0120163	FiO2 activator for 18mm	00011844	ACT 18/22	Instrumentation Industri	B
0120164	Spring loaded FiO2 senso	00011844	MT100	Instrumentation Industri	B
0120165	Replacement `T` assembly	00011844	MT100-TA	Instrumentation Industri	B
0120166	Replacement activator fo	00011844	MT100-A	Instrumentation Industri	B
0120201	Adult MDI Adapter.	00011844	RTC 22-D	Instrumentation Industri	B
0120203	Adult MDI Adapter.	00011844	RTC 23-D	Instrumentation Industri	B
0120204	Paediatric MDI Adapter.	00011844	RTC 15-D	Instrumentation Industri	B
0120205	Paediatric MDI Adapter.	00011844	RTC 15-P	Instrumentation Industri	B
0120208	MDI Adapter.	00011844	RTC 21-D PK 50	Instrumentation Industri	B
0120402	`T` adapter. 22mm I.D. -	00011844		Instrumentation Industri	B
0120103	`T` adapter: 15mm paedia	00070006			Needs Grading
0120130	Connector 15mm O.D. - t	00070006			Needs Grading
0120131	Connector 15mm I.D./22m	00070006			Needs Grading
0120133	Connector 22mm I.D./30m	00070006			Needs Grading
0120130	Connector 15mm O.D. - t	8195			Needs Grading
0120131	Connector 15mm I.D./22m	8195			Needs Grading
0120133	Connector 22mm I.D./30m	8195			Needs Grading

Comments on Suppliers:

no longer selling our T pieces,
supplier reviews not required

Sales Information

Stock Reference	Description	2016	2017	2018	2019	2020	2021	2022
0120090	Oxygen sensor O ring.							
0120098	Oxygen sensor flow diverter O ring 15mm							
0120099	Oxygen Sensor Flow Diver							
0120100	`T` adapter. 22mm I.D. -							
0120103	`T` adapter: 15mm paedia							10
0120106	`T` adapter. 22mm I.D. -							
0120108	`T` adapter. 22mm O.D. -							
0120109	`T` adapter non rebreat							
0120110	Perfusion Circuit `T` Adapter.							
0120121	FlowCheck							
0120125	Connector: 22mm I.D. - 22mm I.D.							
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.							
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm							
0120128	Connector - 15mm I.D. - 22mm I.D.							
0120129	Connector - 22mm O.D - 30mm O.D.							
0120130	Connector 15mm O.D. - t							10
0120131	Connector 15mm I.D./22m							10
0120133	Connector 22mm I.D./30m							
0120139	Adapter 15mm I.D. - 10m							
0120140	Adapter 15mm I.D. - 15m							
0120141	Adapter 15mm I.D./22mm							
0120142	Adapter 15mm I.D./22mm O.D. -							
0120149	Adapter 15mm I.D. - 10mm I.D							
0120150	Adapter 15mm I.D. - 15mm I.D							
0120151	Adapter 15mm I.D./22mm O.D. -							
0120152	Adapter 15mm I.D. - 15m							
0120153	Adapter 15mm I.D./22mm							
0120159	Adapter 15mm I.D. - 10m							
0120160	FiO2 sensor adapter.							
0120161	FiO2 activator for small							
0120162	FiO2 activator for 15mm							
0120163	FiO2 activator for 18mm							
0120164	Spring loaded FiO2 senso							
0120165	Replacement `T` assembly							
0120166	Replacement activator fo							
0120200	Adult MDI Adapter.							
0120201	Adult MDI Adapter.							
0120202	Adult MDI Adapter.							
0120203	Adult MDI Adapter.							
0120204	Paediatric MDI Adapter.							
0120205	Paediatric MDI Adapter.							
0120206	MDI Adapter - Replacement Rubber Cap.							

Stock Reference	Description	2016	2017	2018	2019	2020	2021	2022
0120207	MDI Adapter.							
0120208	MDI Adapter.							
0120300	Wye Connector							
0120301	Wye Connector with pressure port.							
0120302	Wye Connector with temperature probe							
0120303	Wye Connector with temperature probe							
0120304	Temperature probe port cap.							
0120305	Wye connector 60 degrees.							
0120306	Wye connector 90 degrees.							
0120307	Wye connector 60 degrees.							
0120310	Auto PEEP measurement device.							
0120400	`T` adapter. 22mm I.D. - 22mm O.D.							
0120401	`T` adapter. 22mm I.D. - 22mm O.D.							
0120402	`T` adapter. 22mm I.D. -							

Comments on Sales Information:

no new sales

Countries Review

Country	2016	2017	2018	2019	2020	2021	2022
UK							[X]

Comments on Sales to Countries:

no new sales

Comments on Risks with Sales to Countries:

no new sales

Returns and Q.A. Fails Review

Stock Reference	Fault	2016	2017	2018	2019	2020	2021	2022
0120100	No Fault Return To Stock	1						
0120100	Unchecked - Returned To Stock							
0120106	New							
0120108	Unchecked - Returned To Stock							
0120126	No Fault Return To Stock							
0120130	No Fault Found			15				
0120131	Unchecked - Returned To Stock							
0120402	No Fault Found					1		

Comments on Returns:

no issues in the repair system

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

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
32075	T Adaptors Instructions for Use / User Manual BE 117 Non Rebreath...	04/02/20
30396	Instrumentation Industries - Sterilization and Disinfection Rec...	24/07/19
22626	T Adaptors Instructions for Use User Manual T Adapter User inf...	14/10/17
15718	T Adaptors Instructions for Use User Manual BE-117	22/09/15
15717	T Adaptors Instructions for Use User Manual RTC-21-A	22/09/15
15716	T Adaptors Instructions for Use User Manual RTC-15-D	22/09/15
15710	T Adaptors Instructions for Use User Manual III Instructions f...	22/09/15
8947	T Adaptors Instructions for Use / User Manual Tapers	18/10/11

Comments on User Instructions:

no changes to ifu

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15715	T Adaptors Labels T Label warning	22/09/15
9169	No accessory labels	18/10/11
7689	T Adaptors Labels	15/02/11

Comments on Labels:

no changes to labels

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
96348	Instrumentation Industries Inc - ISO 13485 Certificate	09/08/22
72799	T Adaptors Clinical Trials Reports Reviews and Post Market Surve...	21/10/21

Comments on Document Changes:

just file maintenance updates

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 16

ID	Subject
36	0120100
06	E01-002171 Flow diverters
05	E01-002171 Flow diverters
04	E01-002171 Flow diverters
32	Envitec MySign O Oxygen Monitor
3	Leaflet Leaflet Maxtec Oxygen Monitors 3rd Checking Stage
31	Leaflet Leaflet/Catalogue: Lead-free sensors Queries
53	Leaflet Maxtec Monitors Leaflet 2nd Checking Stage
5	Leaflet Oxygen Monitoring Booklet Leaflet Designed
7	Marketing Schedule Maxtec Flowcheck Datasheet to L and Intrastats
9	Marketing Schedule Maxtec Flowcheck Inform staff of release and provide key points
48	Oxygen Monitoring Catalogue inc LF sensors: 1st Checking Stage
15	PAQ PAQs: Maxtec Missing Info: MaxO2 ME
51	Price List NeoPEEP Price List Price List Signed off by Director
9	Send item on Sale Or Return MX300 on SOR737 to Manchester Royal Infirmary Obtain purchase order or arrange return of goods
01	Tom Thumb Review 8th November 2017 - Discontinued Variants

Comments on Issues:

no issues around our T pieces, only other manufacturers,

Comments on Risks with Issues:

no risks found

VIAMED Stock Meeting - Stock Queries

0120100

Issue ID #242536

Date Created 17/Nov/2021

Issued To: Steve Nixon

Completed Status: 02 Aug 2022

Notes:

Added by Zoey Teal sent to Steve Nixon

This part number is showing on the current GBP pricelist for AX300 spare parts linked to this part number.
Please can you update the price list and description to re the certification?

17 Nov 2021 Zoey Teal

Just noticed that part number 0120399 is not on the price list. Please can this be added also?

19 Nov 2021 Steve Nixon

Priority Changed From 5 To 2

Issue Hidden on 15 Mar 2022 by Zoey Teal - until 16/04/22 (Was hidden until : 01 Jan 1970)

Issues:242536

VIAMED Stock Meeting - Any Other Business

E01-002171 Flow diverters

Issue ID #275906

Date Created 27/Oct/2022

Issued To: Ryan Swaine

Completed Status: 27 Oct 2022

Notes:

Copy Issue Main Issue #275904

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

We provided 2000 x 0120099 flow diverters to Envitec on VST invoice RST37785-1 23/6/22. They have now been replaced with the Envitec version E01-002171.

Originally 2000 x Teledyne flow diverters were loaned from Vandagraph stock and supplied to Envitec via VST. Replacement flow diverters addressed to Viamed and now received by Viamed are to be handed over to Vandagraph.

Issues:275906

VIAMED Stock Meeting - Any Other Business

E01-002171 Flow diverters

Issue ID #275905

Date Created 27/Oct/2022

Issued To: Derek Lamb

Completed Status: 28 Oct 2022

Notes:

Copy Issue Main Issue #275904

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

We provided 2000 x 0120099 flow diverters to Envitec on VST invoice RST37785-1 23/6/22. They have now been replaced with the Envitec version E01-002171.

Originally 2000 x Teledyne flow diverters were loaned from Vandagraph stock and supplied to Envitec via VST. Replacement flow diverters addressed to Viamed and now received by Viamed are to be handed over to Vandagraph.

Issues:275905

VIAMED Stock Meeting - Any Other Business

E01-002171 Flow diverters

Issue ID #275904

Date Created 27/Oct/2022

Issued To: Catherine Spence

Completed Status: Still Outstanding

Linked Files

27 Oct 2022 Envitec invoice - Proforma Invoice_Viamed_191022

Notes:

Added by Steve Nixon sent to Catherine Spence

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

We provided 2000 x 0120099 flow diverters to Envitec on VST invoice RST37785-1 23/6/22. They have now been replaced with the Envitec version E01-002171.

Originally 2000 x Teledyne flow diverters were loaned from Vandagraph stock and supplied to Envitec via VST. Replacement flow diverters addressed to Viamed and now received by Viamed are to be handed over to Vandagraph.

Issues:275904

VIAMED Sales And Marketing - Any other business

Envitec MySign O Oxygen Monitor

Issue ID #142332

Date Created 10/Apr/2019

Issued To: Steve Hardaker

Completed Status: 08 Nov 2021

Notes:

Copy Issue Main Issue #142330

Added by Steve Nixon sent to Catrin Hird

As discussed please prepare technical and marketing files for the MySign O.

Catrin, please generate a leaflet and section on the web site.

I'll confirm the pricing soon. I have provisionally added a Euro distributor price (for Medivent via Ryan).

Opera Envitec

0111276 1001825 MySign O

0120100 T-Adapter

0120399 46-006005 T-Adapter. Pack of 5

0120092 Flow diverter (single unit)

0120093 01-002173 Flow diverter. Pack of 10

0121350 Oxygen sensor cable

0121351 1001801 Clamp

0121352 1001829 Power supply

0121354 1001830 Operating manual CD

0121353 1001815 Data cable

0110560 01-00-0114 Oxygen sensor

0131900 1001764 Integrated stand (replacement part)

0191207 Leaflet

Envitec leaflet on their web site.

Look at Pro-Act web site.

15 Apr 2019 Steve Hardaker

Have started a project in the project manager and a technical file, which I will add to as information is located or generated.

15 Apr 2019 Steve Nixon

Additional parts

0131901 1001734 Rechargeable battery

0121355 1002080 Software

15 Apr 2019 Steve Nixon

Provisional price list calculations attached.

05 Nov 2021 Steve Hardaker

Reviewed and checked all docs in Technical File are the latest versions.

Issues:142332

Marketing Job Logger - Marketing Job Logger

Leaflet Leaflet Maxtec Oxygen Monitors 3rd Checking Stage

Issue ID #55183

Date Created 17/Dec/2014

Issued To: Steve Nixon

Completed Status: 14 Nov 2022

Linked Files

29 Jan 2015 Maxtec Oxygen Monitors

Notes:

Catrin Hird 17/12/2014 Issue Generated
Leaflet Leaflet Maxtec Oxygen Monitors 3rd Checking Stage

17 Dec 2014 Catrin Hird

Next Action Changed From To Steve Nixon Please provide part numbers for:
R218P09 - Rubber overmold for Handi
Maxtec Oxygen Monitor leaflet

06 Jan 2015 Catrin Hird

Rubber overmold to be added to Opera as 0121305
Leaflet part number still required.

14 Jan 2015 Catrin Hird

Part numbers received.

All rechecked - with SN for sign off

27 Jan 2015 Catrin Hird

Next Action Changed From Steve Nixon To General Amended version given to SH for checking will reopen issue when done.

29 Jan 2015 Catrin Hird

Next Action Changed From General To Steve Nixon Signed off by SH, please check version on your desk or attached and sign off.
Thanks

04 Feb 2015 Catrin Hird

Amends received and handed back to SN for checking along with self generated price list (awaiting 3 prices 0121305, 0120121, 0111265) from stock group Catrin Hird - Maxtec Monitor Leaflet

04 Feb 2015 Catrin Hird

Added prices to Opera price list for 0120105, 0120109, 0120110 which were missing.

05 Feb 2015 Catrin Hird

SN signed off

Issues:55183

Marketing Job Logger - Marketing Job Logger

Leaflet Leaflet/Catalogue: Lead-free sensors Queries

Issue ID #148731

Date Created 03/Jul/2019

Issued To: Steve Nixon

Completed Status: 14 Nov 2022

Linked Files

20 Aug 2019 Oxygen Monitoring Catalogue 2019-08 WIP

Notes:

Catrin Hird 03/07/2019 Issue Generated
Leaflet Leaflet/Catalogue: Lead-free sensors Queries

03 Jul 2019 Catrin Hird

Next Action Changed From To Steve Nixon Please can you confirm the following:

Output for:

R-23V

R-23Vi

R-43V

R-47V

Warranty for 0111002 UFO 130-2 PCB

Do we have compatibility information yet for the ITG LF sensors?

What are the pack quantities we are allowed to sell the t pieces etc in as need to include in the catalogue.

03 Jul 2019 Catrin Hird

Last query is on issue 147122

20 Aug 2019 Catrin Hird

Query for notes given - Page 20, OOM 102 should be OOMLF102 - can not see this? Page 20 is itg.

We do have a spare page available but due to the layout it would not work to have benefits of Lead-free at the front as it would make all following pages out of sync. I have left them as is for now with a blank page at the back - see what you think.

Once happy I will go through full checking again and provide to SJH for proofing.

Notes from SN completed:

0111002 12 months warranty

R-23 & R-23Vi 24-32 uA

R-43V 25-38 mV

R-47V 9-13.5 (2 channels)- remove output difference statement.

Page 22, add MOX-20 Resmed Elisee, 0110707 MLF-60HC 410040

Standard T adapter blue changed to 0120399

PP1968 changed to 0120124

Quantities:

0120092 - 1

0120093 - 10

0120399 - 5
0120124 - 1
0120174 - 50
0120175 - 35
0120176 - 40
0120177 - 45
0120178 - 50
0120179 - 35

Updated text to page 38 for flowsensors - due to space I have been able to put this back to a full page on Flow sensors.

Front cover - added Autumn 2019

Removed -

0120104
0120108
0120109
0121205
T adapter external T 15-22
Perfusion circuit
0120164
0120165
0120166
0120130
0120131
0120133

Hard copy provided with "Information/Amends Sheet"

Issues:148731

Marketing Job Logger - Marketing Job Logger

Leaflet Maxtec Monitors Leaflet 2nd Checking Stage

Issue ID #163553

Date Created 28/Jan/2020

Issued To: General

Completed Status: 14 Nov 2022

Linked Files

28 Jan 2020 Maxtec Monitors Leaflet 2020-01-28

29 Jan 2020 Maxtec Monitors Leaflet 2020-01-29

29 Jan 2020 Maxtec Monitors Leaflet 2020-01-29 v2

Notes:

Catrin Hird 28/01/2020 Issue Generated
Leaflet Maxtec Monitors Leaflet 2nd Checking Stage

28 Jan 2020 Catrin Hird

Next Action Changed From To Steve Hardaker
Priority Changed From 5 To 0 Please find attached updated Maxtec Monitors leaflet.

Superseded 0120100 with 0120399.

Removed 0120105 0120107.

Hard copy with proof sheet provided.

29 Jan 2020 Catrin Hird

Updated leaflet as per the Oxygen Monitoring catalogue as per our discussion.

Hard copy and proof sheet provided to SJH.

Attached to issue.

29 Jan 2020 Steve Hardaker

Leaflet looks fine but the price list that you provided still has a lot of the discontinued items on it. eg 0120100, 0120105, 0120107 etc. Either the stock group hasn't been amended or you may have printed me the wrong one?

29 Jan 2020 Steve Hardaker

Next Action Changed From Steve Hardaker To Catrin Hird 0121200 - Universal mounting clamp does not fit onto the MaxO2 ME, the table on page 3 requires updating.

The FAQ for 0121200 correctly states that the screw thread is not long enough (I physically checked that this is true).

Note: we had already corrected this on the main oxygen monitoring catalogue but you may need to check whether this info appears elsewhere.

29 Jan 2020 Catrin Hird

Next Action Changed From Catrin Hird To Steve Hardaker Thank you, I have left on the reverse page and removed from the table.

I believe we have only done something like this in the catalogue, I don't think we have done else where.

Updated copy attached.

29 Jan 2020 Steve Hardaker
No further amends. Signed and returned.

04 Feb 2020 Catrin Hird

Next Action Changed From Steve Hardaker To General

Issues:163553

Marketing Job Logger - Marketing Job Logger

Leaflet Oxygen Monitoring Booklet Leaflet Designed

Issue ID #57805

Date Created 31/Mar/2015

Issued To: Jonathan Connor

Completed Status: 14 Nov 2022

Notes:

Catrin Hird 31/03/2015 Issue Generated

Leaflet Oxygen Monitoring Booklet Leaflet Designed

31 Mar 2015 Catrin Hird

Next Action Changed From To Jonathan Connor Please can I have one of each of the following for photos:

0120160

0120161

0120162

0120163

01 Apr 2015 Catrin Hird

Received with thanks

01 Apr 2015 Jonathan Connor

all scanned, will return the others to stock as I have them now

Issues:57805

Marketing Job Logger - Marketing Job Logger

Marketing Schedule Maxtec Flowcheck Datasheet to L and Intrastats

Issue ID #53707

Date Created 30/Oct/2014

Issued To: Derek Lamb

Completed Status: 14 Nov 2022

Linked Files

30 Oct 2014 Flowcheck spec sheet

Notes:

Catrin Hird 30/10/2014 Issue Generated
Marketing Schedule Maxtec Flowcheck Datasheet to L and Intrastats

30 Oct 2014 Catrin Hird

Next Action Changed From To Derek Lamb Please add to intrastats

30 Oct 2014 Derek Lamb
Done intrastats

20 Nov 2014 Catrin Hird

Next Action Changed From Derek Lamb To Steve Nixon flowcheckDataSheet.e.pdf
in z: for L:

03 Mar 2015 Catrin Hird

Next Action Changed From Steve Nixon To Derek Lamb Can't find in Intrastats - part number 0120211 or
under flowcheck

04 Mar 2015 Derek Lamb
In-line Aerosol Tee Adapter. Pack of 25???

think you mean 0120211,
added the stock link, should now show in intrastats.

The technical file works a couple of ways with relating to linking to stock, to actively show against a part
number i have to link them. so in future Ill need to know which stock numbers are to be linked to a document
when i upload them

10 Mar 2015 Catrin Hird
We both got it wrong, its 0120121

11 Mar 2015 Derek Lamb
linked correctly done

11 Mar 2015 Catrin Hird
Thanks

Issues:53707

Marketing Job Logger - Marketing Job Logger

Marketing Schedule Maxtec Flowcheck Inform staff of release and provide key points

Issue ID #57099

Date Created 03/Mar/2015

Issued To:

Completed Status: 14 Nov 2022

Notes:

Catrin Hird 03/03/2015 Issue Generated

Marketing Schedule Maxtec Flowcheck Inform staff of release and provide key points

03 Mar 2015 Catrin Hird

Created Related Issue #57100

Added by Catrin Hird sent to Emily Hanson

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

The Maxtec Flowcheck is ideally suited for checking the output; flow and oxygen concentration, of an oxygen concentrator.

The product is for use in conjunction with the Maxtec MAXO2 range and the Handi+.

The product is part number 0120121 and is £36.50 - now live on our website.

Datasheet is attached or can be found in L, Datasheets, Oxygen Monitoring.

It will currently not a stocked item and will be available to order from Maxtec (4-6 weeks lead time).

03 Mar 2015 Catrin Hird

See related issue

Issues:57099

Marketing Job Logger - Marketing Job Logger

Oxygen Monitoring Catalogue inc LF sensors: 1st Checking Stage

Issue ID #147848

Date Created 20/Jun/2019

Issued To: General

Completed Status: 14 Nov 2022

Linked Files

28 Aug 2019 Oxygen Monitoring Catalogue 2019-08-28 proof1

09 Sep 2019 Oxygen Monitoring Catalogue 2019-09-09 proof2

09 Sep 2019 Oxygen Monitoring Catalogue 2019-09-09 proof3

09 Sep 2019 Oxygen Monitoring Catalogue Signed off by SJH 2019-09-09

09 Oct 2019 Oxygen Monitoring Autumn 2019 2019-10-09 v1

Notes:

Catrin Hird 20/06/2019 Issue Generated

Leaflet Leaflet/Catalogue: Lead-free sensors 1st Checking Stage

28 Aug 2019 Catrin Hird

Next Action Changed From To Steve Hardaker

Subject Changed From Leaflet Leaflet/Catalogue: Lead-free sensors 1st Checking Stage

Subject Changed To Oxygen Monitoring Catalogue inc LF sensors: 1st Checking Stage Please find attached latest copy of the Oxygen Monitoring Catalogue.

All information is correct apart from awaiting text from Steve regarding the Benefits for the lead-free for each manufacturer.

Hard copy with proof sheet provided.

05 Sep 2019 Steve Hardaker

Next Action Changed From Steve Hardaker To Catrin Hird p1 - SN suggests trying different design style as the white box looks `stuck on`, and to my eyes its not really aligned with the other elements on the page. Is the white background fixed? if not, perhaps try the lighter blue?

p2 - standardise on lower case for oxygen sensors.

p5 - UFO-130-1 & UFO-130-2 datasheet says 3.4V +/- 0.4V at 100% oxygen, I think we need that last bit and it looks like we've always specified this incorrectly.

p8 - 2nd to last paragraph: add comma, change `of` to `for` so it reads "in preparation for this,"

p10 - 0110707 - missing image

p11 - SN has suggested 2 Envitec tagline bulletpoints, added to draft.

Note: I have checked the specs against the datasheets but have only checked the Envitec lead-free range for 0110800 - 0110808 as we don't seem to have the rest of the spec sheets on L drive. Have asked SN if he can get them and add to L.

One final thing, I'm not sure the "incorporating lead-free" logo on the front works, it seems like it should clearly state "range now incorporates lead-free sensors" or similar, but that would involve a minor re-design to that bottom corner. Perhaps one for discussion with you, SN and me next week.

Have put back on your desk with proofing sheet.

09 Sep 2019 Catrin Hird

Next Action Changed From Catrin Hird To Steve Hardaker Sorry there is a mix up, you have put notes for the sensor leaflet on the catalogue issue. Have updated 147847.

This issue is for the catalogue.

09 Sep 2019 Catrin Hird
Updated as per leaflet

09 Sep 2019 Steve Hardaker

Next Action Changed From Steve Hardaker To Catrin Hird p10 & 11 - Can you fit "@ 100% oxygen" directly after the output spec? The footer on p11 seems too remote.

p32 - 0120127 - Description incorrect, check the I.D. / O.D. details.

p33 - 0120140 - Not the correct part number for this item.

p38 - Image is black & white

p39 - Change General Purpose to lower case, 2 instances

09 Sep 2019 Catrin Hird

Next Action Changed From Catrin Hird To Steve Hardaker Updated.

Image for flowsensors is b& due to flowsensor leaflet, SN wanted the images to be similar rather than one colour and one not..

09 Sep 2019 Steve Hardaker

Suggested changing to colour images of flowsensors, unless there was a valid reason for using the black and white ones. Otherwise, no amends.

08 Oct 2019 Catrin Hird

Next Action Changed From Steve Hardaker To Steve Nixon Updated images.

Also amended catalogue title so reflects colour change on the leaflet version.

Attached to issue and provided to SN for sign off.

Steve N. Please proof and sign off asap, required for Medica.

09 Oct 2019 Catrin Hird
Redesigned front cover.

Reorder and remove some information from cross reference page (rename).

Hard copy with proof sheet provided to SN. Attached.

11 Oct 2019 Catrin Hird

Next Action Changed From Steve Nixon To General Signed off and added to L

Issues:147848

Marketing Job Logger - Marketing Job Logger
PAQ PAQs: Maxtec Missing Info: MaxO2 ME
Issue ID #253615
Date Created 09/Mar/2022
Issued To: Steve Nixon
Completed Status: Still Outstanding

Notes:

Catrin Hird 09/03/2022 Issue Generated
PAQ PAQs: Maxtec Missing Info: MaxO2 ME

09 Mar 2022 Catrin Hird

Next Action Changed From To Steve Nixon MaxO2 ME Missing Items

Spare parts price list

Working life
Reprocessing cycles
Support guaranteed

Manufacturers Product Liability insurance

10 Mar 2022 Steve Nixon
Requested from Maxtec

28 Mar 2022 Catrin Hird

Spare parts price list - awaiting parts clarification & 0120094/0120398 pricing (this is so it will add to the list, not sending pricing for spare parts).SN SKYPE

Hi, the FAQ and the price list description do not match... i.e. they say different adapters. Please can you review and amend as required as I'm not sure which is correct. Thanks

11 May 2022 Catrin Hird
PAQ uploaded, above still applicable.

22 Aug 2022 Steve Nixon
You state: 0120094/0120398

Do you mean 0120094/0120095? If so:
0120094 Is just a spare O ring
0120095 Is the flow diverter with O ring

Which FAQ are you referring to?

23 Aug 2022 Catrin Hird
List is from page 11 of the user manual.

FAQ re included accessories. 0120095/0120099.

28 Oct 2022 Catrin Hird

The initial query regarding pricing for 0120094 & 0120398 has been rectified as pricing was added in Sept 2022.

FAQ

The MAXO2 ME includes the following accessories: 1 x 0110452 MAX-550E oxygen sensor 1 x 0131700

Sensor cable 1 x 0120100 T adapter* 1 x 0120095 Flow diverter *When supplied as an accessory with the monitor this is covered by the CE mark of the monitor. For replacements sales see 0120399 (pack of 5) which are CE marked.

Price List

0131700 - not showing

0120095 - not showing

Instruction Manual Page 11 states R228P87 but 0131702 says it should be R228P08 - does this require an amend by manufacturer?

PAQ requirements - spare parts list to be review to cover above.

Issues:253615

Marketing Job Logger - Marketing Job Logger

Price List NeoPEEP Price List Price List Signed off by Director

Issue ID #108651

Date Created 21/Nov/2017

Issued To: Steve Nixon

Completed Status: 14 Nov 2022

Linked Files

21 Nov 2017 NeoPEEP Price List 2017-11-21

21 Nov 2017 NeoPEEP Price List 2017-11-21 B

27 Nov 2017 NeoPEEP Price List 2017-11-27

28 Nov 2017 NeoPEEP Price List 2017-11-28

26 Mar 2018 NeoPEEP Price List 2018-03-26

Notes:

Catrin Hird 21/11/2017 Issue Generated

Price List NeoPEEP Price List Price List Signed off by Director

21 Nov 2017 Catrin Hird

Next Action Changed From To Katie Evans UK Price list generated and attached and provided to KE for review (copy also saved in Z Checking).

SN - prices missing for following parts and currencies:

0120151 0003 International End User Euros
0120151 0005 International End User USD
0120153 0002 UK Distributor
0120153 0003 International End User Euros
0120153 0004 International Distributor Euros
0120153 0005 International End User USD
3210013 0003 International End User Euros
3210013 0005 International End User USD
3210023 0003 International End User Euros
3210023 0005 International End User USD
3210067 0002 UK Distributor
3210067 0003 International End User Euros
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3210067 0006 International Distributor USD
3210068 0002 UK Distributor
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3210068 0006 International Distributor USD
3210069 0002 UK Distributor
3210069 0003 International End User Euros
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3210069 0005 International End User USD
3210069 0006 International Distributor USD
3210070 0003 International End User Euros
3210070 0005 International End User USD
3210071 0003 International End User Euros
3210071 0005 International End User USD
3210073 0003 International End User Euros
3210073 0005 International End User USD
3210074 0003 International End User Euros

3210074 0005 International End User USD
3210076 0003 International End User Euros
3210076 0005 International End User USD
3210077 0003 International End User Euros
3210077 0005 International End User USD

22 Nov 2017 Katie Evans
Checked GBP end user lists and returned to your desk

27 Nov 2017 Catrin Hird
Reviewed and updated.
Hard copy of proof sheet provided.
Digital copy in Z:

28 Nov 2017 Catrin Hird

Next Action Changed From Katie Evans To Steve Nixon Updated and given to SN for review with proof sheet.

Also saved in Z:Information for LibraryIn Checking with SN

25 Jan 2018 Catrin Hird
GBP price list signed off. Above currencies need prices applying to be able to produce other price lists.

29 Jan 2018 Catrin Hird
The following prices are still missing:

0120153 0005 International End User USD
3210067 0002 UK Distributor
3210067 0006 International Distributor USD
3210068 0002 UK Distributor
3210068 0004 International Distributor Euros
3210068 0006 International Distributor USD
3210069 0002 UK Distributor
3210069 0004 International Distributor Euros
3210069 0006 International Distributor USD

12 Mar 2018 Catrin Hird
Above prices still missing

26 Mar 2018 Catrin Hird
Prices all been updated with Tom Thumb Price List.
Resaved into Z:Information for LibraryIn Checking with SNNeopeep Price Lists

Hard copies and proof sheet provided to SN, for checking. Zip file attached to this issue.

03 May 2018 Catrin Hird
SN signed off verbally. He adding to L drive.

Issues:108651

Marketing Job Logger - Marketing Job Logger

Send item on Sale Or Return MX300 on SOR737 to Manchester Royal Infirmary Obtain p

Issue ID #77799

Date Created 25/Aug/2016

Issued To: Katie Evans

Completed Status: 14 Nov 2022

Notes:

Steve Hardaker 25/08/2016 Issue Generated

Send item on Sale Or Return MX300 on SOR737 to Manchester Royal Infirmary Obtain purchase order or arrange return of goods

25 Aug 2016 Steve Hardaker

Next Action Changed From To Katie Evans

Priority Changed From 5 To 0 Please can you arrange for a new Opera account to be set up and a Proforma sent to Tommy Muirhead. They work for a company sub-contracted to, and working in, Manchester Royal Infirmary Perfusion Dept.
UK End-user pricing.

Invoice address:

Manchester Perfusion Practice
12D Woodford Road
Bramhall
Cheshire
SK7 1JJ

Delivery address:

Perfusion Department
First Floor Theatres
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL

Proforma to include:

5x 0111235 MX300 with 0110017 sensors

5x 0121182 Rail clamps

5x 0120110 Perfusion Circuit T adapter

5% discount to be applied to all items (will need director approval)

Please make reference on Proforma that 1x 0111235, 1x 0110017, 1x 0120110 already supplied on Sale Or Return, ref. SOR737.

Note: that SOR is on as Manchester Royal, whoever invoices this will have to have those barcodes returned from SOR to stock so that we can scan them to the order on the new account (obviously, he will just keep the physical goods).

The Proforma needs to be emailed to Tommy Muirhead at oxygenator2000@yahoo.co.uk

Any questions, please ask, thanks.

25 Aug 2016 Katie Evans

No problem, done just waiting for director to sign

25 Aug 2016 Steve Hardaker

Company number 03522198 - listed on Companies House website. If you need any further info, you can

email Tommy or call him on 0161 276 5778. Thanks.

30 Aug 2016 Katie Evans

Thank you, updated. Proforma was sent last week

31 Aug 2016 Steve Hardaker

Urgent Flag Changed To On Just checked the proforma, it appears that the 5x 0120110 were missed off. Just chased Tommy and he says that we should have received the order by now, has it come in?

31 Aug 2016 Steve Hardaker

I checked Opera and the awaiting action tray, the order doesn't appear to have arrived.

I tried calling Denise Read (0161 491 5797) as Tommy advised that Denise will be raising the order, but she must be on lunch.

Please can you contact her to see if the order has been raised, and if not, advise that we need to amend the proforma to include 5x 0120110 and re-send it (we don't have her direct email address).

If it has already been raised and sent, she will need to raise another order for 5x 0120110 (note: 1x 0120110 already supplied on SOR737), thanks.

31 Aug 2016 Katie Evans

Denise said she has not raised the order yet. Sent the amended proforma

Issues:77799

VIAMED Sales And Marketing - Sales

Tom Thumb Review 8th November 2017 - Discontinued Variants

Issue ID #107601

Date Created 08/Nov/2017

Issued To: Catrin Hird

Completed Status: 14 Nov 2022

Linked Files

20 Nov 2017 Infant Resuscitation Catalogue 2017-11-20

20 Nov 2017 Tom Thumb Price List 2017-11-20 DRAFT WEIGHTINGS ISSUE OUTSTANDING WITH DL

21 Nov 2017 Tom Thumb Price List 2017-11-21 DRAFT WEIGHTINGS ISSUE OUTSTANDING WITH DL

21 Nov 2017 Tom Thumb GBP Price List 2017-11-21

21 Nov 2017 Tom Thumb GBP Price List 2017-11-21 b

21 Nov 2017 Infant Resuscitation Catalogue 2017-11-21

21 Nov 2017 Infant Resuscitation Catalogue 2017-11-21 b

Notes:

Copy Issue Main Issue #107599

Added by Steve Nixon sent to Derek Lamb

As of today we will discontinuing non relevant Tom Thumb (Infant T-piece Resuscitator) devices, either due to using non blended gas, specials or low/no sales. See attached list for further details.

Variants retained & continued:

0310030 TT-480

Required for general sales and for use with resuscitation cabinets

0310094 TT-480 with pole mount

Continue, but monitor - low sales to date.

Catrin, please edit price lists, leaflet, catalogues & web site accordingly, i.e. just retain 0310030 TT-480

Once reviewed and appraised, may add 0310094.

20 Nov 2017 Catrin Hird

All variants of Tom thumb apart from 0310030, removed from website.

Infant Resus Catalogue - removed tom thumb variants and updated image - still needs work regarding acrylics being removed - attached current artwork for review by SN - i.e. page 9 has some white space left - would you like further information regarding specifications to be included (even though we are trying to steer away from that in catalogues)?!?

Amended pages 14/15 regarding "also available" pages.

Hard copy provided to SN with proofing sheet.

Price List

9901-22 shown on price list - is 0330191 correct replacement part? Have updated price list to generate from Intrastats - issue with DL regarding weightings not working (108584) but attached for reference.

The following prices as required to update other price list (if required)... Hard copy provided to SN with proofing sheet.

0310030 0005 International End User USD

0330191 0002 UK Distributor

0330191 0004 International Distributor Euros

0330191 0006 International Distributor USD

3210011 0003 International End User Euros

3210011 0005 International End User USD

3210013 0003 International End User Euros

3210013 0005 International End User USD
3210067 0002 UK Distributor
3210067 0003 International End User Euros
3210067 0005 International End User USD
3210067 0006 International Distributor USD
3210068 0002 UK Distributor
3210068 0003 International End User Euros
3210068 0004 International Distributor Euros
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3210068 0006 International Distributor USD
3210069 0002 UK Distributor
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3210071 0005 International End User USD
3210073 0003 International End User Euros
3210073 0005 International End User USD
3210074 0003 International End User Euros
3210074 0005 International End User USD
3210076 0003 International End User Euros
3210076 0005 International End User USD
3210077 0003 International End User Euros
3210077 0005 International End User USD

21 Nov 2017 Catrin Hird

9901-22/0330191 removed from price list as requested.

Incorrect part numbers given for silicone adapters, should have been 0120150 (instead of 0120149),
0120152 (instead of 0120159).

Updated prices required list...

0120151 0003 International End User Euros
0120151 0005 International End User USD
0120153 0002 UK Distributor
0120153 0003 International End User Euros
0120153 0004 International Distributor Euros
0120153 0005 International End User USD
0310030 0005 International End User USD
3210013 0003 International End User Euros
3210013 0005 International End User USD
3210023 0003 International End User Euros
3210023 0005 International End User USD
3210067 0002 UK Distributor
3210067 0003 International End User Euros
3210067 0005 International End User USD
3210067 0006 International Distributor USD
3210068 0002 UK Distributor
3210068 0003 International End User Euros
3210068 0004 International Distributor Euros
3210068 0005 International End User USD
3210068 0006 International Distributor USD
3210069 0002 UK Distributor
3210069 0003 International End User Euros
3210069 0004 International Distributor Euros
3210069 0005 International End User USD
3210069 0006 International Distributor USD
3210070 0003 International End User Euros
3210070 0005 International End User USD
3210071 0003 International End User Euros

3210071 0005 International End User USD
3210073 0003 International End User Euros
3210073 0005 International End User USD
3210074 0003 International End User Euros
3210074 0005 International End User USD
3210076 0003 International End User Euros
3210076 0005 International End User USD
3210077 0003 International End User Euros
3210077 0005 International End User USD

21 Nov 2017 Catrin Hird

Next Action Changed From Catrin Hird To Katie Evans Please review price list for correct descriptions.

Hard copy provided and saved in Z Checking, proof sheet provided.

21 Nov 2017 Catrin Hird
Updated and reattached.

21 Nov 2017 Catrin Hird
SN - Infant Resus catalogue provided to you for checking with proof sheet.

27 Nov 2017 Catrin Hird
Price list updated (still waiting for product weighing coding to be updated by DL #108584. Hard copy with proof sheet with KE.

28 Nov 2017 Catrin Hird
Created Related Issue #109225
Added by Catrin Hird sent to Steve Nixon
Price list updated and sent to SN for review with proof sheet. Pricing missing as follows:

0120151 0003 International End User Euros
0120151 0005 International End User USD
0120153 0002 UK Distributor
0120153 0003 International End User Euros
0120153 0004 International Distributor Euros
0120153 0005 International End User USD
0310030 0005 International End User USD
3210013 0003 International End User Euros
3210013 0005 International End User USD
3210023 0003 International End User Euros
3210023 0005 International End User USD
3210067 0002 UK Distributor
3210067 0003 International End User Euros
3210067 0005 International End User USD
3210067 0006 International Distributor USD
3210068 0002 UK Distributor
3210068 0003 International End User Euros
3210068 0004 International Distributor Euros
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3210069 0003 International End User Euros
3210069 0004 International Distributor Euros
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3210069 0006 International Distributor USD
3210070 0003 International End User Euros
3210070 0005 International End User USD
3210071 0003 International End User Euros
3210071 0005 International End User USD
3210073 0003 International End User Euros
3210073 0005 International End User USD
3210074 0003 International End User Euros
3210074 0005 International End User USD

3210076 0003 International End User Euros
3210076 0005 International End User USD
3210077 0003 International End User Euros
3210077 0005 International End User USD

Also saved in: Z:Information for LibraryIn Checking with SN

28 Nov 2017 Catrin Hird

Next Action Changed From Katie Evans To Catrin Hird See related issue.

28 Nov 2017 Catrin Hird
see related issue

Issues:107601

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 :

T piece, too generic to find any negative reports.

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 :

T piece, too generic to find any negative reports.