

CUSTOMER COMPLAINT REPORT			CCR No.	155
			Date:	15/8/23
Customer:	Saadat / initially sold to Trionara	P.O.	TR-PO-230105-1	
File No.:	CID10114	Invoice:	RVM141219-1	
Address:	Laxfiskevagen 6, Partille, 43338, Sweden			
Product:	4420826 VersaStream sampling lines	Despatched:	17 Apr 2023	
Serial No.(s):	Batches 28223.02.07, 28223.02.8	Issue:	304005	
Manufacturer / Supplier	Viamed / Bluepoint			
MHRA Risk assessment carried out Yes No				
<u>Nature of Complaint:</u> Leaking gas from around the Nomo connector. Customer believes that this is something to do with the size of the O-ring as the Nomoline appears fractionally shorter than the original Masimo and swapping the O-rings over resolves the problem.				
<u>Result of Investigation:</u> SN advised them to test with the calibration gas as specified in the manual and that we will look to make some slight dimensional changes to a multi cavity moulding tool. The issue seems to only happen when the sampling line connector is rotated in the instrument. 22 Sep 2023 Derek Lamb: This is not a Viamed CCR, Information has been forwarded on to the manufacturer, Bluepoint Medical, for review. Bluepoint decided to not change the tooling as they have had no other reports of problems, stating: "We did not change because we never had any issue." "We sell this product now since more than 8 years without any negative feedback."				
Signed:			Date:	
<u>Corrective Action:</u>				
<u>External:</u>				
10/08/2024 Bluepoint has opted to take no further action.				
<u>Internal:</u>				
Viamed will monitor returns and customer feedback for any other occurrences.				
There have been no further complaints from Saadat.				
Signed:			Date:	
MHRA Informed?	YES	NO		QC 12