Vygon (UK) Ltd
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Date: 10-01-2014

Dear Customer

Re. Vygon Protect-A-Line range of IV extension lines – Syringe pump 'occlusion' alarms

The recent change in the anti-syphon valves of the Vygon Protect-A-Line range marginally increased the mean resistance of these valves. The opening pressure of the new anti-syphon valve varies from 210 millibar (approximately 158mmHg) to 290 millibar (approximately 218 mmHg), whereas the earlier version, the 0832.xxR range, had an average opening pressure of 155mmHg (approximately 207 millibar). This places the Protect-A-Line range on a par with most other protected lines on the market, whereas the average opening pressure of the earlier version was approximately 20% lower.

This change was made in February 2013, at which time Vygon released a Product Modification Notice to our customers, informing them of the increase in resistance and advising that in some circumstances this may require the alarm pressure of the pump to be increased. We did not envision the necessary increase to be greater than from 300mmHg (the normal pump alarm setting) to 400mmHg, as the resistance of the valves is less than 300mmHg.

After the Modification Notice was released there followed a period of several weeks when there were no reports of occlusion alarms relating to the Protect-A-Line range. Then we began to receive reports that the new valves were believed to be causing occlusions. At the time we ran further tests, which confirmed that, while the lines had a marginally higher resistance, this was consistent and should not contribute a greater resistance to the syringe pump delivery system than most similar products on the market.

At the time that the Modification Notice was released for these products the MHRA made the unusual decision to release a MDA on the basis of this notice. It is our understanding that this led some users to believe the resistance of these lines to be unusually high. When we began to receive an increased number of reports of occlusion alarms we became concerned that confusion arising from the MHRA alert may have resulted in customers identifying our products as the root cause of this issue when it was possible that the syringes used were the source of the additional resistance. We mentioned this concern in our responses to a number of our customers, including NHS Greater Glasgow & Clyde.

In response to this, NHS Greater Glasgow & Clyde performed their own investigation into the management of occlusion alarms, the findings of which were presented at the National Services Scotland 'Safe and effective infusions, Management of occlusions and "False Alarm"' seminar on 2nd December 2013, which was attended by representatives from Vygon (UK) Ltd.

GG&C assessed a number of anti-syphon valves, including those used in the Protect-A-Line range, which they found all exhibited consistent levels of resistance. They also eliminated the possibility that needle-free connectors may be a contributory factor. Several makes of syringe were assessed, all of which exhibited a degree of variation in the level of 'stiction' exhibited (static friction, i.e. resistance resulting from a combination of friction and the adhesive/elastic properties of the syringe plunger). The products of one widely used syringe manufacturer exhibited the highest levels of stiction and in several instances exhibited stiction levels higher than the equivalent of 300mmHg. A recent change in the plunger design of these syringes has resulted in a greater variance in stiction, which GG&C concluded made it difficult to set alarm levels in advance. We underastand that the syringe manufacturer is aware of this issue and is currently manufacturing replacement stock.

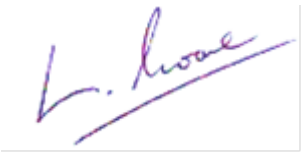
We understand that this problem has the greatest impact on PCAs as the initial stiction level has to be overcome every time the pump is activated. The resistance contributed by the anti-syphon valves in the lines used is constant and limited compared to that shown to be exhibited by syringes, hence any alarm that occurs part way through the infusion is very likely to result from variation in syringe stiction.

Vygon is aware that the lower opening pressure of the original Protect-A-Line valves was a desirable attribute and this has been communicated to the manufacturer. A supplier for a less resistant anti-syphon valve has now been found. The new product is currently part-way through the verification process and we hope to be able to start supplying Protect-a-Lines with this replacement valve early in 2014.

In summary, it is now clear that the majority of non-patient-related occlusion alarms are caused by the pump interpreting friction based syringe resistance as an increase in back-pressure. Protected extension lines should still be considered an important part of an IV patient safety system.

We hope that this information is useful but please do not hesitate to contact us if you require further clarification.

Yours sincerely



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