

MHRA Ref: 2013/005/020/401/001

Report: Viamed 31 / 07 / 2013

Part number: 4310001

Description: Flowsensor SpiroTrue A (pack of 5)

Batch number 7001131B



Our risk assessment resulted in determining that there was no risk to the patient, as the flow sensors snapped - either upon removal from service, or possibly during cleaning procedures. The flow sensors are designed as single patient use, so would either be disposed of, or cleaned and tested for further use on the same patient.

The only complaint of 'broken' sensors has been from a single customer. On further investigation, used sensors have shown 'micro' cracks in the moulding. Since the 30th May 2013 when this was first brought to my attention, Viamed has not received any further complaints of broken flow sensors.

The original supplier of the ABS plastic in Germany suffered from a fire at their factory last year, and therefore until recently production and supply of the raw material was disrupted. In the meantime an alternative ABS material from another supplier was utilized, as assurances were given that this material was directly compatible to that of the original supplier's.

Viamed decided a product recall was not required. We have however ceased supplying any further batches of flow sensors until manufacturing could resume using the original ABS raw material. The supplier of the original material has now resumed manufacturing, so the next production batch of sensors will be manufactured from this material. In view of this we do not envisage any further incidents. In with each box of sensors we include user and cleaning instructions.

Using the original ABS material, an initial limited number of examples of the flow sensors have been produced - so that we could confirm our findings. Two sensors from this batch have also been supplied to Dorset County Hospital for evaluation.

Regards

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