# Investigation into reported lifespan problems with Viamed Flowsensor A

A number of customers have reported that Viamed Flowsensor A (part number 4310001) does not last anywhere near as long as the Dräger original.

To investigate the issue, I have met with the EBME Manager at Liverpool Heart and Chest Hospital and ITU Technician at Leicester Royal. The following are questions and answers from those meetings.

**Q: What symptoms / failures are the flowsensors displaying?**

A: The Viamed 4310001 flowsensors has an overall lifespan of approximately half that of the Dräger Spirolog. In addition, it demands much more frequent calibration, occasionally as often as every 6-12 hours even with a brand new sensor.

**Q: How can the customer verify these lifetime claims?**

A: Liverpool Heart and Chest Hospital moved from Dräger to Viamed sensors and the usage, which was consistent, immediately doubled. The increased usage remained consistent at the higher level until the Trust's Head of Accounts queried the doubling of the quantities being ordered and demanded that the Trust return to the Dräger sensor, at which point the usage halved immediately. The customer is 100% convinced that demonstrates longevity issues with the Viamed sensor.

The ITU Technician at Leicester Royal is responsible for changing all the failed flowsensors on ITU and felt it was overwhelmingly obvious that the Viamed ones do not last as long as Dräger.

**Q: Which model of Dräger vents are involved?**

A: LH&C is mostly using Evita 4s, but a few older Dura series are still in service, both display premature failures with Viamed flowsensors. These vents are used in an Intensive Care environment and use 1 flowsensor on the expiratory side of the circuit.

**Q: Which Dräger flowsensors have they been using to compare the performance?**

A: Exclusively the Spirolog sensor. They have never used the Infinity ID flowsensor, and the vent has no way to identify whether the flowsensor is an original Dräger or a compatible flowsensor.

**Q: How frequently are the vents calibrated?**

A: The Evita 4 forces a calibration every 24 hours or when the flowsensors drifts out of calibration. Hospital protocol demands calibration every time the vent is used on a different patient. Some consultants recalibrate after each setting change. Both Dräger and Viamed sensors are subject to the same calibration procedures.

**Q: Can the failures be traced to a specific vent or vents?**

A: It is not possible that specific vents are a factor; in both of these Trusts, the flowsensors are rotated through various vents due to the Trust's practice of removing the ventilator respiratory block after each patient and reprocessing it. The flowsensor and respiratory block are then put onto a different vent that has already been reprocessed. As such, the flowsensor is never installed back onto the vent that it has just been removed from.

**Q: How are the flowsensors cleaned?**

A: Both Viamed and Dräger flowsensors are soaked in 70% Isopropyl Alcohol for minimum of 1 hour then dried in a drying cupboard (low heat, slightly above room temperature).

**Q: Are the flowsensors cleaned prior to first use?**

A: No. Neither Viamed nor Dräger flowsensors cleaned prior to first use.

**Q: How are Dräger flowsensors packaged?**

A: Heat-sealed, clear plastic bags. Dräger previously used unsealed paper bags similar to Viamed, but have moved to plastic bags in the last few years. LH&C speculated whether the sealed bag might indicate a modified atmosphere inside the packaging, I have since tested for this and found it to be air.

**Q: Are medications present in the gases flowing through the flowsensor?**

A: Yes, frequently at both hospitals. Medication is introduced via an external nebuliser, LH&C use both synchronised nebulisation, which attempts to minimise the quantity of medication passed down the expiratory limb, and continuous nebulisation, which does not. As a result, flowsensors on the expiratory limb can be exposed to gases containing medication, which can sometimes be observed as a white, crystalline deposit on the inside of the flowsensor.

**Q: Which medications are commonly used?**

A: LH&C regularly uses the following medications through nebulizers:

| Active ingredient | Trade-names |
|---|---|
| Salbutamol | Ventolin, Ventoline, Ventilan, Aerolin, Ventorlin, Asthalin, Asthavent, Proventil, ProAir, Salamol, Airomir, Ventosol, Asmol |
| Ipratropium bromide | Atrovent, Apovent, Ipraxa, Aerovent, Rinatec |
| Budesonide | Rhinocort, Rhinosol, Pulmicort |
| Saline solution | |

**Q: Does the Viamed flowsensor undergo more conditioning cycles during the calibration process than the Dräger?**

A: No, there is just one cycle regardless of which sensor is installed.

**Q: There is a reported problem with the wiring loom on some Dräger vents causing intermittent connection with the flowsensor, could this be affecting the sensors?**

A: No. All the affected models have had the wiring loom replaced by Dräger.

**Q: Do sensors that are removed from service after failing to calibrate recover?**

A: Yes, they can often be cleaned and returned to service, but still exhibit the same behaviour, often failing and repeating this cycle a number of times, which is causing additional work for the technicians.

**Q: Are anaesthetic ventilators also affected?**

A: The technician at LRI was not sure but LH&C said not: Viamed flowsensors used in anaesthetic vents can last up to 12 months.

**Q: What is the difference between the environment created when the flowsensors are used in an ICU vent and an anaesthetic vent, and could this be a factor?**

A: Anaesthetic vents creates a dry, stable atmosphere, with a constant breathing pattern; ICU vents are often used with high humidity and erratic breathing cycles due to being used to wean patients: defined as the gradual reduction of ventilatory support and its replacement with spontaneous ventilation.

## Avenues for further investigation

### Environmental factors

It worthy of investigation to compare the different conditions and environments that the sensors are exposed to in order to determine whether any or all of the conditions are contributing to failures:

- Erratic breathing cycles: causing repeated heating/cooling cycles on the wire, pins and solder joints, as opposed to steady cycles during anaesthesia. Could this cause temporary or permanent degradation in performance?

- High humidity: possibly degrading components or some electrical conductivity issue?

- Medication: could deposits on the wire, pins and solder joints prematurely degrade the materials, affecting the performance?

- Medication: could deposits on the wire form a coating that changes the wires operational characteristics, affecting the performance?

### Component specification factors

Are all the components manufactured to the exact same specification and from the exact same materials as the Dräger originals, including the wire, pins and solder?

### Manufacturing standards factors

Are the flowsensors manufactured to the exact same standards as the Dräger originals? Could the following factors be an issue?

- Damage to the wires during manufacturing.

- The tension in the wires once attached to the pins: is this achieved manually or by an automated process that can be shown to be repeatable? Variable tension may affect the overall length and operational characteristics of the wire.

- Exact placement of the wires on the dead centre of the pins: is this repeatable and monitored? Variable positioning may affect the overall length and operational characteristics of the wire.

- Quality of solder joint

- Quality of the bonding process between plastic component parts.

## Viamed's ongoing investigation

Samples were provided from different batches to different hospitals, with serial number tracking to analyse the failures and longevity.

Reports came back of premature failures, both electronic and physical. Some customers reported that the sensors were developing cracks and splitting after only one use.

No customers have reported any increase in longevity from the trial sensors.

I am making efforts to obtain a number of samples of failed sensors for further investigation, and have specifically asked for sensors that may have failed due to the deposit of medication not to be cleaned so that the build-up on these sensors can be investigated.