



Steve Hardaker <viamed.steve.hardaker@gmail.com>

RE: Defective R30-V O2 sensor - Leaking from

1 message

Medical Devices Safety Officer <MedicalDevicesSafetyOfficer@nbt.nhs.uk>

15 September 2017 at 15:06

To: "steve.hardaker@viamed.co.uk" <steve.hardaker@viamed.co.uk>

Cc: Emma Broom <Emma.Broom@nbt.nhs.uk>, Adam Chabowski <Adam.Chabowski@nbt.nhs.uk>, Craig Wheeler <Craig.Wheeler@nbt.nhs.uk>, Guyan Perera <Guyan.Perera@nbt.nhs.uk>, Lee Browne <Lee.Browne@nbt.nhs.uk>, Robert Kelly <Robert.Kelly@nbt.nhs.uk>, Steven Bartlett <Steven.Bartlett@nbt.nhs.uk>

Hi Steve,

We have just found another O2 sensor which is leaking from the electrical connector. S/No. V103325. This is part of the same batch as the previous two returned sensors.

How would you like me to proceed.

Please can you give me assurances that the sensors that we will order have ordered since as safe to use.

Many thanks,

Paul.

Anaesthetic Service Head – MDSO

Clinical Equipment Services, Gate 10 Level 6

North Bristol NHS Trust, Southmead Hospital, Westbury on Trym, Bristol, BS10 5NB. Tel 0117 4146069

From: Paul Derman **On Behalf Of** Medical Devices Safety Officer

Sent: 07 September 2017 12:42

To: 'steve.hardaker@viamed.co.uk'

Cc: Emma Broom; Adam Chabowski; Craig Wheeler; Guyan Perera; Lee Browne; Robert Kelly; Steven Bartlett

Subject: Defective R30-V O2 sensor - Leaking from

Dear Steve,

As per our conversation, please find attached pictures and documents detailing the design changes, leaking O2 sensors and missing 'O' ring. There appears to be two variations of the sensor inside the blue housing. The larger sensor fits exactly to the side of the blue housing and uses two 'O' rings to

seal the sensor (gas side & electrical connection side). The newer smaller internal sensor requires three 'O' rings. The smaller version uses a large 'O' ring to centralise the sensor in the housing.

The two faulty, small sensors variant, had sequential serial numbers V103329 & V103330. The fault appears when the internal Envitec sensor (small version) is displaced from the internal seating 'O' rings front and back (gas side & electrical connection side) where the gas can leak out of the electrical port. After the V103330 sensor casing was opened, Steve, investigating Engineer, found the large 'O' ring was missing from this batch. This 'O' ring seems to hold the smaller sensor in position and keep the smaller two 'O' ring sealing the sensor. The V103329 sensor was not opened to ensure you can look into the fault.

Many thanks,

Paul.

Anaesthetic Service Head – MDSO
Clinical Equipment Services, Gate 10 Level 6
North Bristol NHS Trust, Southmead Hospital, Westbury on Trym, Bristol, BS10 5NB. Tel 0117 4146069

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