Gmail 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> 23 November 2017 at 10:53
To: Steve Hardaker <steve.hardaker@viamed.co.uk>, Medical Devices Safety Officer <MedicalDevicesSafetyOfficer@nbt.nhs.uk>
Cc: "derek.lamb@viamed.co.uk" <derek.lamb@viamed.co.uk>, Emma Broom <Emma.Broom@nbt.nhs.uk>

Hi Steve,

Thank you for comprehensive investigation report. I am happy with your conclusion and have received the replacement stock. We have one failure since the original email was sent and this was from the same batch S/No. V103325. No other issue have been detected during machine leak events. We have included an O2 blanking plug in our service kit to isolate the O2 sensor during the leak testing process.

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: viamed.steve.hardaker@gmail.com [mailto:viamed.steve.hardaker@gmail.com] **On Behalf Of** Steve Hardaker
Sent: 13 October 2017 15:42
To: Medical Devices Safety Officer
Cc: derek.lamb@viamed.co.uk
Subject: Re: Defective R30-V O2 sensor - Leaking from

Dear Paul,

We have just received the investigation report from the manufacturing facility, which confirms that the inner sensor used in the manufacturing of the R-30V oxygen sensor was changed to a smaller version in November 2015. The centering O-ring that you observed was not present at this time as the design passed the necessary drop-test requirements.

Following this manufacturing change, it was identified that the inner sensor could under certain conditions (i.e. if subjected to a physical shock in excess of that used during drop-tests) move and permit leakage of gas through the sensor housing.

In July 2016, the centering O-ring was added to prevent the inner sensor from moving. The serial numbers for the changes are as follows:

- **Serial numbers up to and including V10304**5 - used a large, inner sensor that filled the sensor housing

- Serial number V103046 to V103370 - used a smaller inner sensor with no O-ring

- Serial number V103371 onward - corrective action applied and all subsequent sensors have a centering O-ring.

For the 5 sensors that you returned on returns reference SRS66190, we will take the following actions:

- s/n V103005 - unaffected by the issue and out of warranty. I understand that this sensor had already been removed from service, so no action is required and the sensor will be disposed of.

- s/n V103329 & V103330 - missing the centering O-ring, sensors will be replaced under warranty.

- s/n V103471 & V103760 - O-ring present but destroyed during the investigation, sensors will be replaced under warranty.

It should be noted that sensors within the affected serial number range do incorporate additional sealing O-rings to prevent gas leakage and, when the corrective action was applied, a product recall was not deemed necessary. If you have any further sensors that are exhibiting leaks, please could I ask you to return them to us for investigation?

We have investigated this as a customer complaint under our ISO quality management system, the complaint reference is CCR150. If you have any further information, comments or queries, please let me know, quoting this reference.

Please could you confirm receipt of this email for our records? Thank you in advance.

Regards,

Steve Hardaker
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On 7 September 2017 at 12:42, Medical Devices Safety Officer <MedicalDevicesSafetyOfficer@nbt.nhs.uk> wrote:

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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