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

RE: Defective R30-V O2 sensor - Leaking from

Steve Hardaker <steve.hardaker@viamed.co.uk> 15 September 2017 at 17:05
Draft To: Medical Devices Safety Officer <MedicalDevicesSafetyOfficer@nbt.nhs.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>, Steve Nixon <steve.nixon@viamed.co.uk>, sales@viamed.co.uk
Bcc: derek.lamb@viamed.co.uk, Main Account <office@viamed.co.uk>

Hi Paul,

This sensor (s/n V103325) is part of a batch of 8 that were supplied on 20/9/16 with date codes 2016-07. All of the sensors that you have dismantled from that batch so far appear to be missing the large centering O-ring, so if you want to return any or all of those using the same returns number of **SRS66190**, we will replace them under warranty as a precaution.

We have not yet received the sensors back that you reported last week, or they have not yet been processed into our returns system, so the investigation has not progressed very far as yet. However, to date, the only reported problems are with sensors date coded 2016-07, of which you purchased 8 on 20/9/16, your order ref L723473:

V103325 Date Code 2016-07
V103326 Date Code 2016-07
V103327 Date Code 2016-07
V103328 Date Code 2016-07
V103329 Date Code 2016-07
V103330 Date Code 2016-07
V103331 Date Code 2016-07
V103332 Date Code 2016-07

The following batch that you purchased on 1/12/16, your order ref L779208, comprised the following serial numbers:

V103468 Date Code 2016-09
V103469 Date Code 2016-09
V103470 Date Code 2016-09
V103471 Date Code 2016-10
V103472 Date Code 2016-10
V103473 Date Code 2016-10

Of that batch, you identified s/n V103471 as having the large, centering O-ring. We reasonably expect that the batch dated 2016-10 will have the O-ring and not suffer the same problem. There is still no evidence for batch 2016-09, so both of these batches need verifying under our ongoing investigation.

I will be away from the office from Monday until Friday of next week, so I will have to hand this over to my colleague, Steve Nixon (Commercial & Technical Director), who has been on leave this week but will be back on Monday to commence the investigation. I have cc'd Steve in on this email.

If you need replacements urgently, please can you document the serial numbers of all of the sensors that you are sending back and email the information including the **customer complaint reference CCR150** to sales@viamed.co.uk and cc to steve.nixon@viamed.co.uk and our sales admin team will arrange to ship replacements in advance for all of them as agreed by our MD today.

I hope to pick up on this upon my return but trust that my colleagues will handle this and keep you up-to-date in my absence.

Regards,

Steve Hardaker
UK Sales Manager
Viamed Ltd.

Visit us at the Emergency Services Show, Birmingham N.E.C., Hall 5, Stand J22 from Wednesday 20th to Thursday 21st September 2017.
The UK's largest exhibition dedicated to the Emergency Services.

Please note: I will be away from the office from Monday 18th until Friday 22nd September.
Emails will remain in my inbox and I will respond upon my return.
If your enquiry is urgent, please contact Viamed on 01535 634542 or email info@viamed.co.uk with the word 'URGENT' in the subject line.

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On 15 September 2017 at 15:06, Medical Devices Safety Officer <MedicalDevicesSafetyOfficer@nbt.nhs.uk> wrote:

> 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