



Steve Nixon <steve.nixon.viamed@googlemail.com>

AW: Update on Sedana test reports

1 message

Froehlich, Heidi <h.froehlich@bluepoint-medical.com>
To: Steve Nixon <steve.nixon@viamed.co.uk>

13 March 2024 at 17:37

Thank you Steve, looks good😊

Best regards,

Heidi

Von: Steve Nixon <steve.nixon@viamed.co.uk>
Gesendet: Mittwoch, 13. März 2024 16:35
An: Froehlich, Heidi <h.froehlich@bluepoint-medical.com>
Betreff: Fwd: Update on Sedana test reports

As discussed and for your files.

Regards

Steve

----- Forwarded message -----
From: **Steve Nixon** <steve.nixon@viamed.co.uk>
Date: Tue, 12 Mar 2024 at 20:15
Subject: Update on Sedana test reports
To: Bernd Lindner <b.lindner@bluepoint-medical.com>

Hi Bernd

Further to our discussion last week I have attached the relevant Sedana test reports. They have proved 24hr testing with both ISO & SEVO, 72hr testing with ISO (with varied the positioning of control/Nafion/Viamed lines), then two sets of 72hr compatibility testing using ISO & SEVO to prove material compatibility and no material degradation.

Original report from March 2021

Ref. 8090121313V

24hr test report using Isoflurane & Sevoflurane

134114.10188 4421516 - ISO and SEVO Test Report - 210326_12_03_24

Day 1: 22-03-2021 to 23-03-2021

8hrs Isoflurane 2.0 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

8hrs Isoflurane 4.5 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

8hrs Isoflurane 7.0 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

Day 2: 25-03-2021 to 26-03-2021

8hrs Sevoflurane 4.0 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

8hrs Sevoflurane 7.0 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

8hrs Sevoflurane 10.0 ml/hr infusion rate. Ventilator settings at 250 ml x 20 bpm, 500 ml x 15 bpm, 750 ml x 10 bpm

You previously accepted the test methods and results.

Dated 30-11-2023 to 02-11-2023

Ref. 8090121313V

72hr test report using Isoflurane

VIAMED H-Line 72hr Compatibility Test Report (2)

Day 1 - 24hrs Isoflurane 2.0 ml/hr infusion rate - low settings. Ventilator settings at 750 ml x 12 bpm (4hrs), 250 ml x 20 bpm (4hrs), 500 ml x 15 bpm (16hrs). Results - see section 6.1 page 6 of 10

Day 2 - 24hrs Isoflurane 4.0 - 4.5 ml/hr infusion rate - medium, settings. Ventilator settings at 750 ml x 12 bpm (4hrs), 250 ml x 20 bpm (4hrs), 500 ml x 15 bpm (16hrs). Results - see section 6.2 page 7 of 10

Day 3 - 24hrs Isoflurane 6.0 - 7.0 ml/hr infusion rate - high settings. Ventilator settings at 750 ml x 12 bpm (4hrs), 250 ml x 20 bpm (4hrs), 500 ml x 15 bpm (16hrs). Results - see section 6.3 page 8 of 10

"The overall stability and readability of the Viamed H-Line cannot be faulted, making it a good, compatible alternative to the Nafion line."

"Feedback on the test data provided by Sedana Medical's CMO and Medical Director indicate that there is no clinical significance to such a minor difference in end-tidal concentration (0.1%). There is no relevant risk to patient safety or clinical usage caused by the differences observed between the Viamed H-Line and Nafion Line setup. Overall, it can be confidently stated that the Viamed H-Line offers an accurate and acceptable alternative to the current gas sampling line setup for durations up to 72 hours, as expected based on the initial 24hr Compatibility Test Report (2021)."

Dated 05-02-2024 to 08-02-2024 Isoflurane 72hrs duration

Dated 28-02-2024 to 02-03-2024 Sevoflurane 72hrs duration

72hr test reports to prove material compatibility and no degradation.

VIAMED H-Line 72hr Compatibility Test Report (Additional Data) (1)

"After 72 hours of testing with continuous sampling of both isoflurane and sevoflurane, no material degradation was observed, no residue was observed, no moisture was absorbed by the water trap and no unusual Fet% readings were observed. Overall, the Viamed H-Line performed effectively throughout the 72hr tests, confirming compatibility with the Sedaconda®ACD standard setup."

I will tomorrow morning to discuss.

Regards

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Steve

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