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1. Introduction

The purpose of this test is to determine whether Viamed's "Premium" Gas Sampling Line H is compatible with AnaConDa and the delivery of volatile anaesthetics (Isoflurane and Sevoflurane). This test will compare the performance of Sedana Medical's current recommended gas sampling setup with the proposed Viamed H-Line. Currently, Sedana recommend the use of a standard gas monitoring line such as Intersurgical's Gas Monitoring Line (1.2mm ID Male/Male Luer Lock 2.45m) in combination with a dryer line such as Perma Pure's Nafion Line. The key performance criteria that will be investigated is:

- 1. End-Tidal Concentration (Fet%) Reading** – both lines should display identical Fet% values as they will be placed in series and will use identical Gas Monitors.

2. Test Parameters

Table 1 – Constant Test Settings

| | |
|----------------------------------|--------------------------|
| Inspiratory:Expiratory | 1:2 |
| PEEP | 5 mbar |
| Anaesthetic Agent | Isoflurane / Sevoflurane |
| Bowl Temperature | 37 ± 0.5 °C |
| Chamber Temperature | 37 ± 0.5 °C |
| Sample Flow Rate (Vamos): | 200 ± 20 ml/min |

Table 2 – Variable Test Settings

| Setting | Tidal Volume [mL] | X | Breath Rate [bpm] | | Isoflurane Infusion Rate [mL/h] | Sevoflurane Infusion Rate [mL/h] |
|---------|-------------------|---|-------------------|---|---------------------------------|----------------------------------|
| 1 | 250 | x | 20 | → | 2.0 | 4.0 |
| 2 | 500 | x | 15 | | 2.0 | 4.0 |
| 3 | 750 | x | 10 | | 2.0 | 4.0 |
| 4 | 250 | x | 20 | → | 4.5 | 7.0 |
| 5 | 500 | x | 15 | | 4.5 | 7.0 |
| 6 | 750 | x | 10 | | 4.5 | 7.0 |
| 7 | 250 | x | 20 | → | 7.0 | 10.0 |
| 8 | 500 | x | 15 | | 7.0 | 10.0 |
| 9 | 750 | x | 10 | | 7.0 | 10.0 |

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3. Test Setup



Figure 1 – Test Setup (Picture)

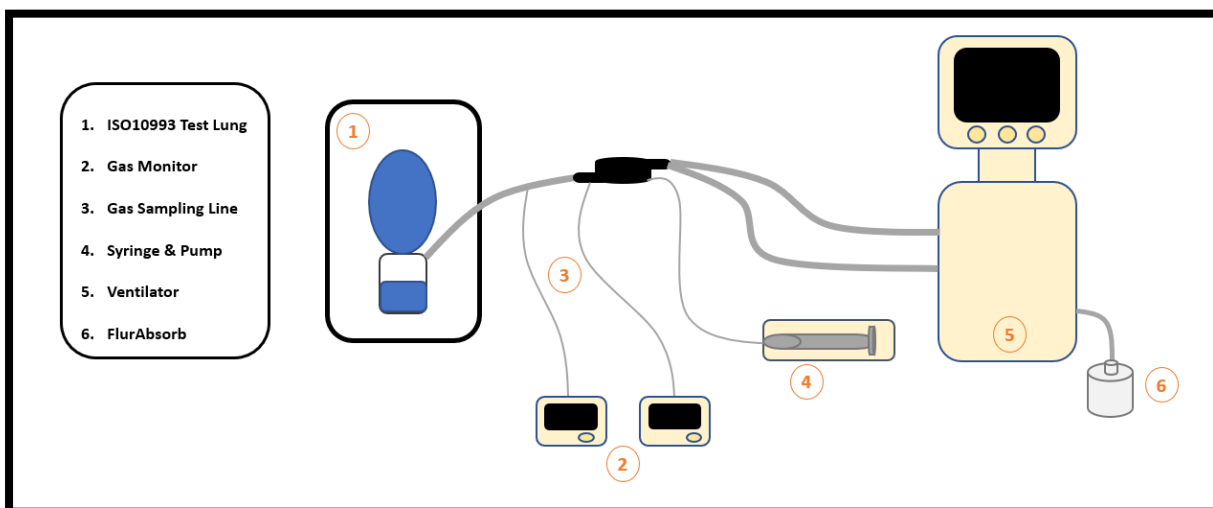


Figure 2 – Test Setup (Diagram)

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4. Test Equipment

4.1 Test Subject

Gas Sampling Line

Model: Viamed H-Line
Reference Number: 8090121313V
Lot Number: S-074-2020-09

4.2 Test Support Equipment

AnaConDa-S (50ml)

Manufacturer: Sedna Medical Ltd.
Reference Number: 26050
LOT Number: N001390

Water Traps (x2)

Manufacturer: Dräger AG
Model: WaterLock2
Reference Number: 6872130
LOT Number: 1000806626

Gas Sampling Line

Manufacturer: Intersurgical Ltd.
Reference Number: 2732000
LOT Number: 31952634

Dryer Line / Nafion

Manufacturer: Perma Pure LLC
Reference Number: 26053
LOT Number: M5121317-01

AnaConDa Syringe

Manufacturer: Sedna Medical Ltd.
Reference Number: 26022
LOT Number: N001233

Isoflurane

Manufacturer: Piramal Critical Care
LOT Number: G145G19A

Sevoflurane

Manufacturer: Piramal Critical Care
LOT Number: S2209109

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Mechanical Ventilator

Manufacturer: Maquet Critical Care AB
Model: Servo-U

Gas Monitor #1

Manufacturer: Dräger AG
Model: Vamos
Date of Manufacture: 10/26/2020

Gas Monitor #2

Manufacturer: Dräger AG
Model: Vamos
Date of Inspection: 05/09/2019

Infusion Pump

Manufacturer: BBraun
Model: Infusomat® Space

Mass Balance

Manufacturer: Kern & Sohn GmbH
Model: KB10K0.05N

Test Lung

Model: ISO 10993

Air Compressor

Manufacturer: Clarke Air Ltd.
Model: SHHHAIR (100/24)

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5. Test Procedure

- Set up the test apparatus as described in figure 1 and figure 2, with the two gas monitoring lines and gas monitors in series.
- Set the ventilator and infusion pump to the first set of parameters outlined in table 1 and 2. (Give a bolus of 1.2ml for the initial start-up).
- Compare the two gas sampling lines by recording the peak Fet% displayed on both gas monitors at 60-minute intervals. (NOTE: since no CO₂ is used during the test, the gas monitor cannot determine an accurate end-tidal concentration. The gas monitor will read live Fet% at various sample points. The end-tidal concentration is determined as the peak Fet% observed at each breath.)
- Adjust the ventilator / infusion pump settings as outlined in the results section below.
- Repeat the same procedure for each of the 9 parameter settings until the 24hr test is complete.
- Complete the procedure outlined above using both isoflurane and sevoflurane.

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6. Isoflurane Test Results

| Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|---------------|---|-----------------|-------------------------|-------------------|----------------------|
| 2 mL/hr | 250 mL x 20 bpm | 1.0 | 1.1 | 1.1 | |
| | | 2.0 | 1.1 | 1.0 | - 0.1 |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 0.6 | 0.6 | |
| | | 4.0 | 0.6 | 0.6 | |
| | | 5.0 | 0.6 | 0.6 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 0.3 | 0.3 | |
| | | 7.0 | 0.3 | 0.3 | |
| | | 8.0 | 0.3 | 0.3 | |

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| Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|---------------|---|-----------------|-------------------------|-------------------|----------------------|
| 4.5 mL/hr | 250 mL x 20 bpm | 1.0 | 2.2 | 2.2 | |
| | | 2.0 | 2.4 | 2.4 | |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 1.1 | 1.2 | + 0.1 |
| | | 4.0 | 1.2 | 1.2 | |
| | | 5.0 | 1.2 | 1.2 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 1.1 | 1.0 | - 0.1 |
| | | 7.0 | 1.1 | 1.2 | + 0.1 |
| | | 8.0 | 0.9 | 0.9 | |

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| Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|---------------|---|-----------------|-------------------------|-------------------|----------------------|
| 7 mL/hr | 250 mL x 20 bpm | 1.0 | 3.2 | 3.3 | - 0.1 |
| | | 2.0 | 3.3 | 3.4 | - 0.1 |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 1.6 | 1.6 | |
| | | 4.0 | 1.6 | 1.6 | |
| | | 5.0 | 1.6 | 1.6 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 1.3 * | 1.6 * | + 0.3 |
| | | 7.0 | 1.2 | 1.2 | |
| | | 8.0 | 1.2 | 1.3 | + 0.1 |

* Very unstable data

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7. Sevoflurane Test Results

| 8. Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|------------------|---|--------------|----------------------|----------------|-------------------|
| 4 mL/hr | 250 mL x 20 bpm | 1.0 | 1.1 | 1.1 | |
| | | 2.0 | 1.1 | 1.0 | - 0.1 |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 0.6 | 0.6 | |
| | | 4.0 | 0.6 | 0.6 | |
| | | 5.0 | 0.6 | 0.6 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 0.3 | 0.3 | |
| | | 7.0 | 0.3 | 0.3 | |
| | | 8.0 | 0.3 | 0.3 | |

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| Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|---------------|---|-----------------|-------------------------|-------------------|----------------------|
| 7 mL/hr | 250 mL x 20 bpm | 1.0 | 2.7 | 2.8 | + 0.1 |
| | | 2.0 | 2.7 | 2.6 | - 0.1 |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 1.4 | 1.4 | |
| | | 4.0 | 1.4 | 1.4 | |
| | | 5.0 | 1.4 | 1.4 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 1.3 | 1.3 | |
| | | 7.0 | 1.0 | 1.0 | |
| | | 8.0 | 1.0 | 1.0 | |

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| Infusion Rate | Ventilator Settings | Time [hours] | Viamed Line H [Fet%] | Control [Fet%] | Difference [Fet%] |
|---------------|---|-----------------|-------------------------|-------------------|----------------------|
| 10 mL/hr | 250 mL x 20 bpm | 1.0 | 2.8 | 2.9 | + 0.1 |
| | | 2.0 | 3.0 | 3.0 | |
| | Change ventilator settings at 2.5 hours | | | | |
| | 500 mL x 15 bpm | 3.0 | 1.8 | 1.8 | |
| | | 4.0 | 1.8 | 1.8 | |
| | | 5.0 | 1.8 | 1.8 | |
| | Change ventilator settings at 5.5 hours | | | | |
| | 750 mL x 10 bpm | 6.0 | 1.5 * | 1.7 * | + 0.2 |
| | | 7.0 | 1.4 | 1.4 | |
| | | 8.0 | 1.3 | 1.3 | |

* Very unstable data

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9. Summary of Results




Overall, the Viamed Premium H-Line compared very well to Sedana's control/standard gas sampling line setup (Nafion + Intersurgical). The large majority of the measurements were equal on both lines throughout the two 24hr studies.

The maximum difference observed was 0.1%, with the exception of measurement number 22 during both the isoflurane and sevoflurane studies. This measurement point is considered an outlier due to the extremely unstable data observed on both monitors. It was notably difficult to take an accurate reading at this measuring point due to the unstable data. It is reassuring that both lines quickly stabilised and showed equal readings again during point 23 and 24.

10. Conclusion

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 Sedana Medical's current 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.

| | Date | Time | Signature |
|-----------------------------------|------------|-------|---|
| Isoflurane Test Start: | 22-03-2021 | 09:00 |  |
| Isoflurane Test Complete: | 23-03-2021 | 09:00 |  |
| Sevoflurane Test Start: | 25-03-2021 | 09:00 |  |
| Sevoflurane Test Complete: | 26-03-2021 | 09:00 |  |

| | | |
|---------------------|--|---|
| Written by: | Lyes Djennadi R&D and Manufacturing Engineer |  |
| Reviewed by: | Harry Hennessy Senior R&D Engineer |  |
| Approved by: | Peter Fröberg R&D and Technical Director |  |

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